LifeSync® 2.1 System

User's Manual

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Preface

Introduction

Indications for Use

The LifeSync® Wireless System is indicated for use when ECG monitoring is needed and a wireless cable-free connection is desired between the patient and the ECG monitor. The LifeSync® Wireless System will also transmit the patient respiration waveform for those ECG systems that include a respiration function.

Contraindications

The use of the LifeSync® Wireless System is contraindicated:

- When ECG monitor output may be used to perform a synchronized cardio version or intracardiac monitoring
- When using an internal monitoring device synchronized to an external device; i.e. in electrophysiology
- During use of MRI or PET scan equipment
- When performing external pacing

Intended Use of LifeSync® Wireless System

The LifeSync® Wireless System is intended for use as a radio-frequency signal transmitter and receiver of diagnostic electrocardiographic physiological signals which are displayed on the ECG monitors of various manufacturers' systems that have been validated for compatibility. ECG systems that are not currently wireless in operation will now be able to be used in a wireless fashion by virtue of being connected to the LifeSync® System. The LifeSync® System will also transmit the patient respiration waveform for those ECG systems that include a respiration function.

The LifeSync® System will eliminate the wires between the ECG patient and the ECG monitor and will replace the traditional ECG cable with a radio link. The LifeSync® System will support the standard 5-lead ECG hook-up (via the Continuous Leadwear for monitoring and has the capability to add the remaining V1-V6 precordial leads (via the Discrete Leadwear for 12-lead discrete ECG recording.

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CAUTION: United States Federal law restricts this device to sale, distribution or use by, or on the order of, a licensed medical practitioner.

This User Manual is intended for use by trained clinicians, who are presumed to be familiar with the use of ECG monitoring equipment, and interpretation of vital signs collected and displayed by that equipment.

The LifeSync® Patient Cables and Cable Adapters are intended to be used in conjunction with various patient monitoring equipment such as ECG and EKG.

Caution/Warning Conventions

WARNING: Calls attention to WARNINGS – conditions or practices that could result in personal injury to the patient or the clinician.

CAUTION: Calls attention to CAUTIONS – conditions or practices that could result in damage to the equipment or other property.

NOTE: Calls attention to NOTES – information of particular importance or assistance to the user.

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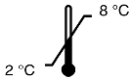
Symbols

The following symbols are used throughout this manual, and/or may appear on LifeSync® Wireless System Components:

⎓	Direct current		Patient Connections are Type CF, protected against defibrillation
	Input		Battery should not be disposed of in fire
	Non-ionizing electromagnetic radiation		ETL listed product
	Consult accompanying documents	Bluetooth	Bluetooth® Wireless Technology
Li++	Lithium ion battery	EC REP	Authorized representative in the European Community
IPX1	Enclosure Protection Drip proof: per EN60529: 1991		Temperature limitation
	Expiration, Use before		Manufacturer
		SN	Serial Number

Safety Information

Warnings

- Explosion Hazard – In accordance with UL 60601-1, which applies to all medical equipment, do not use this device in the presence of flammable anesthetics.
- In order for the LifeSync® LeadWear® Disposable to work properly, the RL / Right Leg / GREEN electrode must be connected to the patient at all times with appropriate electrode attached. Follow electrode manufacturer's guidelines for skin prep prior to placing electrodes on patient.
- LifeSync® LeadWear® Disposable is radiolucent. Using some digital imaging systems, it may be less apparent that LeadWear® Disposable and radiolucent electrodes are outside the body. When attached to LeadWear® Disposable

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snaps, electrodes with opaque posts provide a better indication that LeadWear® Disposable snaps and electrodes are outside the body.

- To ensure patient safety, only LifeSync® LeadWear® Disposable products should be used with the LifeSync® Patient Transceiver. The safety of connecting other devices, leads or cables to the Patient Transceiver has not been evaluated and may present safety hazards. Furthermore, substandard performance may result from the use of incompatible components.
- The LifeSync® Monitor Transceiver should only be connected to patient monitors as illustrated in the System Set Up section of this manual, and only to those monitors that have been validated for compatibility with the LifeSync® and meet ANSI/AAMI EC13:2002 and ANSI/AAMI EC11:1991. Contact LifeSync Corporation for the most current list of validated monitors.
- Only use the approved LifeSync® Power Supply (Model LS-132) in order to ensure that the Patient Monitor (to which the LifeSync® Monitor Transceiver is connected) continues to comply with risk (leakage) current, and EMI/EMC requirements.
- Normal operation of the LifeSync® Wireless System should be verified in the configuration in which it will be used before engaging in use with a patient. Inspect and test the LifeSync® 2.1 Transceivers, rechargeable batteries, and power supply frequently. Do not operate the LifeSync® Wireless System if any system component appears damaged or appears not to function properly. See System Functional Check section of this manual for procedure to verify normal operation.
- If either of the LifeSync® Transceivers detects an unrecoverable fault, the RED Service LED will illuminate continuously, indicating that service is required prior to use of the LifeSync® Transceiver. Do not attempt to use a LifeSync® Transceiver that indicates service is required. When RED service LED is on, the LifeSync® Wireless System will stop working.
- The LifeSync® Wireless System can remain applied to a patient during defibrillation. The ECG signal will be interrupted for no more than a few seconds during defibrillation.
- The LifeSync® Wireless System should not be used to perform a synchronized cardio version, due to signal latency in the radio transmission.
- The LifeSync® Wireless System can be used during procedures using electrosurgery machines. However, even though the LifeSync® Transceivers contain electrosurgical interference suppression filters, increased noise will likely be present while an electrosurgery device is in use. Location of the electrosurgery return pad is very important to minimize interference (be sure to follow electrosurgical manufacturer's guidelines). This effect can be reduced by selecting low impedance electrodes and ECG electrode sites that are remote from the surgical site and electrosurgical return. Avoid electrosurgical surgery burns at the ECG electrodes sites by ensuring proper connection of the electrosurgery return pad, so that the return path cannot be made through the

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ECG electrodes. Care should be taken to prevent physical contact between electrosurgical equipment and any LifeSync® Wireless System component. The ECG and respiration signals will be interrupted for no more than a few seconds if the electrosurgical current path is close to the ECG leads.

- To ensure patient safety, the conductive parts of ECG electrodes, any conductive parts of the LifeSync® LeadWear® Disposable or any other conductive patient applied parts should not contact any other conductive parts, including earth ground, at any time.
- LifeSync® Wireless System and LifeSync® Patient Cables and Cable Adapters should not be used in a Magnetic Resonance Imaging (MRI) suite. Strong magnetic fields may affect the device, causing injury to the patient and/or damage to the equipment.
- The LifeSync® Wireless System and LifeSync® Patient Cables and Cable Adapters can operate in the presence of pacemaker pulses, and will detect and communicate these pulses to the ECG monitor. The LifeSync® Wireless System may miss pacer pulses if high background noise is present. The LifeSync® Wireless System captures signal spikes regardless of whether spikes are due to noise or pacer pulses. If the LifeSync® Wireless System triggers frequently from background noise due to motion artifact, EMI, etc., then pacer pulses could be masked or missed by the LifeSync® Wireless System. See further disclosure of pace maker pulse detection information in the Technical section on page 59 of this manual.
- The LifeSync® Wireless System may decrease the ability of the monitor to detect marginal pacemaker pulses (e.g., pacemaker pulses having amplitudes ≤ 2.0 mV and/or widths ≤ 0.2 ms). If the monitor does not detect the pacemaker pulse, then attempt to change the monitored Lead to a Lead exhibiting a larger amplitude pacemaker pulse. If changing the monitored Lead does not result in pacemaker pulse detection, then switch the patient to a LifeSync® Patient Cables and Cable Adapters.
- The LifeSync® Wireless System should not be used for external pacing.
- Impedance pneumography detects respiratory effort via changes in chest volume. Impedance pneumography can be used to detect central apnea, but apnea episodes with continued respiratory effort, such as obstructive apnea and mixed apnea, may go undetected. Artifacts due to patient motion, mattress shaking or use of electrocautery equipment may also cause apnea episodes to go undetected. Impedance pneumography is not recommended for patients with pacemakers.
- A loss of signal can occur if excess force causes damage to a LifeSync® LeadWear® Disposable that is stretched due to electrode placement on the patient. In the event of an emergency situation where excess force would be applied to the patient (resuscitation) please have a secondary method of monitor readily available to avoid a period of time where the patient is not monitored.

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- When disconnecting the LifeSync® Patient Cables and Cable Adapters, pull on the plug itself, not on the cable.

Cautions

- The LifeSync® Patient Transceiver and LifeSync® Monitor Transceiver are Class 2, Bluetooth devices with a range of 10 meters/30 feet. Range may be reduced from obstructions such as walls, concrete or metal structures. Optimal range of communication is achieved by "line-of-sight" in which both transceivers "see" the other without obstructions. When possible maintain line-of sight to improve range.
- The rechargeable batteries should be removed (from both the LifeSync® Patient Transceiver and the LifeSync® Monitor Transceiver) and stored separately when the system is not in use for extended periods of time.
- Remove the plastic film cover from the rechargeable battery contacts before using.
- Do not autoclave LifeSync® Wireless System components or LifeSync® Patient Cables and Cable Adapters. Do not submerge LifeSync® Wireless System components or LifeSync® Patient Cables and Cable Adapters in any liquid.
- LifeSync® LeadWear® Disposable is radiolucent. Areas of the circuit may show shadows on x-ray or under fluoroscopic imaging.
- The LifeSync® Patient Transceiver and LifeSync® Monitor Transceiver have been tested and shown to comply with FCC Part 15. Any changes or modifications to the LifeSync® Wireless System not expressly approved by LifeSync Corporation could cause LifeSync® Wireless System emissions to exceed those permitted under FCC rules, and would thus void the user's authority to operate the equipment.
- When using a 3 lead patient cable to connect the ECG equipment to the LifeSync® Monitor Transceiver, Welch Allyn Propaq and Philips Viridia monitors will not properly detect and display a lead fail indication if one of the three electrodes (RA, LA, LL) becomes detached from the patient. Note that the monitor will function properly if connected to the LifeSync® Monitor Transceiver with a 5 lead cable.
- Only use the LifeSync® Wireless System and LifeSync® Patient Cables and Cable Adapters with ECG equipment that has been validated for compatibility. Contact LifeSync Corporation Customer Service at 866-ECG-3888 for information on ECG Monitors that are compatible with the LifeSync® Wireless System.
- Medical Electrical Equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in this manual.

Note: Validation testing for additional ECG equipment is ongoing. Please contact LifeSync Corporation at 866-ECG-3888 for the current list of compatible equipment.

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Notes

- A new LifeSync® Replacement Battery (LS-405) is recommended after one year of use.
- All LifeSync® Wireless System components that are applied to the patient are either passive (LifeSync® LeadWear® Disposables) or internally powered (LifeSync® Patient Transceiver).
- All LifeSync® LeadWear® Disposables, Patient Cables and Cable Adapter components that are applied to the patient are passive.
- The LifeSync® Monitor Transceiver can be operated as a Class II device per EN 60601-1 or internally powered.
- This device has been tested and certified to comply with emissions portion of EN 60601-1-2, Medical Electrical Equipment – Electromagnetic Compatibility – Requirements and Tests. Although this device is shielded against Electromagnetic Interference (EMI), it is recommended that electrically radiating devices not be used in close proximity to this device.
- Portable and mobile RF communications equipment can affect the operation of the LifeSync® Wireless System.
- Operation of the LifeSync® Wireless System below minimum amplitude of patient physiological signal may cause inaccurate results.

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Introduction to the LifeSync® Wireless 2.1 System

System Overview

The LifeSync® Wireless System is designed to eliminate the ECG lead wires and cables that connect patients to cardiac monitoring equipment. The system has several components which work together to carry signals from the patient to the monitor.

The lead wire function is replaced by the LifeSync® LeadWear® Disposable Cable Replacement System, which attaches directly to electrodes.

The trunk cable function is replaced by a pair of two-way radios, the LifeSync® 2.1 Patient Transceiver and the LifeSync® 2.1 Monitor Transceiver, which wirelessly transmit and receive ECG and respiration data.

LeadWear® Disposables connect to the LifeSync® Patient Transceiver; the LifeSync® Monitor Transceiver is connected to the ECG monitor.

A LifeSync® Token is used to synchronize the two transceivers; this ensures that the patient's ECG signal is being sent to the correct monitor.

The LifeSync® Patient Transceiver is powered by the LifeSync® Rechargeable Battery. The LifeSync® Monitor Transceiver can also be powered by a LifeSync® Rechargeable Battery for portable use, but is intended to be operated using LifeSync® Power Supply connected to standard AC power when available. While connected to AC power, the LifeSync® Monitor Transceiver functions as a battery charger. When the battery in the LifeSync® Patient Transceiver runs low, it can be quickly exchanged for the fully charged battery in the LifeSync® Monitor Transceiver.

The LifeSync® Patient Transceiver may be placed in a single-patient use Telemetry Pouch to protect it from fluids and other hazardous materials.

In areas where the wireless capability of the LifeSync® Wireless System is not in use, LifeSync® Patient Cables and Cable Adapters are available to connect the LeadWear® Disposable(s) directly to an ECG monitor.

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Unpacking Checklist

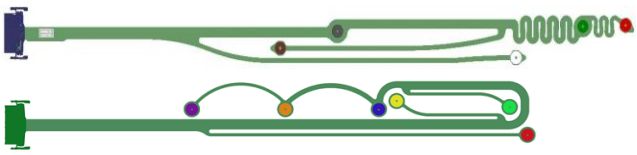
2.1 Patient Transceiver

- ☐ LifeSync® 2.1 Patient Transceiver
- ☐ LifeSync® Rechargeable Battery

2.1 Monitor Transceiver

- ☐ LifeSync® 2.1 Monitor Transceiver
- ☐ LifeSync® Rechargeable Battery
- ☐ LifeSync® Blue synchronization Token
- ☐ LifeSync® Yellow Bedside/Cart configuration Token
- ☐ LifeSync® Green 5/12 Lead configuration Token
- ☐ LifeSync® Mounting Plate
- ☐ Reference Material CD including User's Manual*

LeadWear® Disposable



- ☐ LifeSync® 5 Lead LeadWear® Disposable
- ☐ LifeSync® Precordial LeadWear® Disposable
- ☐ LifeSync® 12 Lead LeadWear® Disposable

** A printed LifeSync® System User's Manual (LS-216) is provided when requested.*

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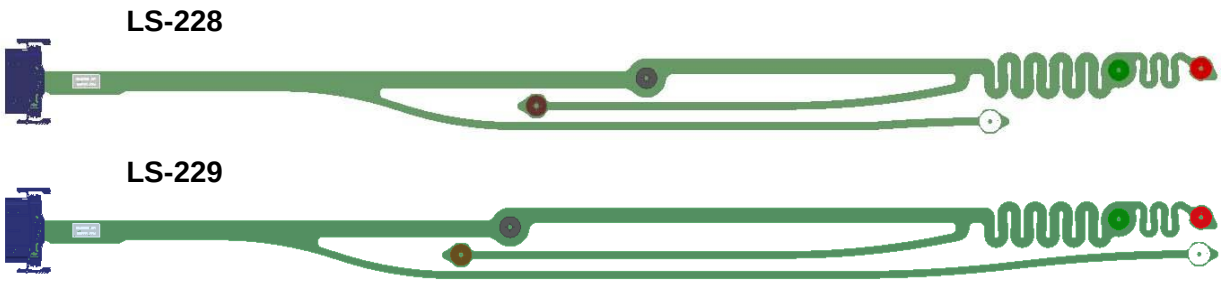
System Components

LifeSync® LeadWear® Disposable

There are two types of LifeSync® LeadWear® Disposable:

5 Lead LeadWear® Disposable	BLUE Connector	For continuous 5 lead ECG monitoring
Precordial LeadWear® Disposable	GREEN Connector	Used in combination with the 5 Lead LeadWear® Disposable for 12 lead ECG monitoring

5 Lead LeadWear® Disposables



5 Lead LeadWear® Disposables				
Part #	**Size**	**V Lead**	**RA-LA**	**LA-LL**
LS-228	7	12"	<24"	<16"
LS-229	9	14"	<28"	<21"

Precordial LeadWear® Disposables

Precordial LeadWear® Disposables							
Part #	**Size**	**Description**	**V1 – V2**	**V2 – V3**	**V3 – V4**	**V4 – V5**	**V5 – V6**
LS-238A	7	V1-V6	<24"	<6"	<7"	<4.5"	<4.5"

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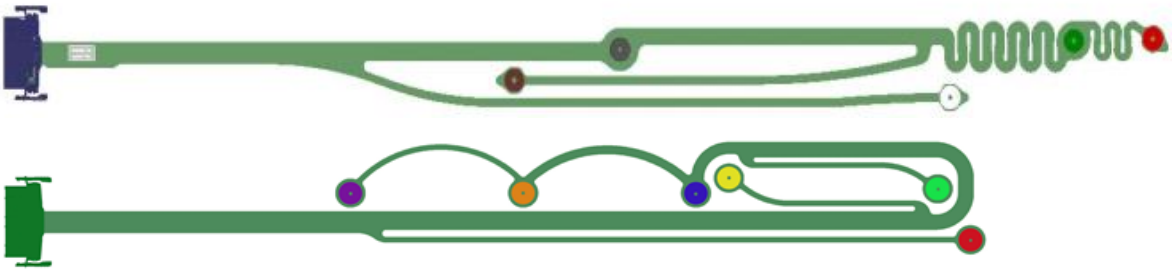
12 Lead LeadWear® Disposables



12 Lead LeadWear® Disposables			
Part #	**Size**	**5 Lead**	**Precordial**
LS-208A	7	LS-228	LS-238A

LeadWear® Disposables are packaged three ways:

5 Lead	One 5 Lead LeadWear® Disposable
12 Lead	One 5 Lead LeadWear® Disposable and One Precordial LeadWear® Disposable
Precordial	One Precordial LeadWear® Disposable

LeadWear® connectors are color-coded to ensure proper connection to the LifeSync® Patient Transceiver: BLUE connectors on the 5 Lead LeadWear® Disposable and GREEN connectors on the Precordial LeadWear® Disposable.

NOTE: LifeSync® LeadWear® Disposables are non-sterile.

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2.1 Patient Transceiver

LifeSync® LeadWear® Connector Ports:
Color-coded ports for attachment of the LeadWear® Disposable:
Blue for the 3/5 LeadWear® Disposable.
Green for the Precordial LeadWear Disposable.

LifeSync® Token Port:
Insert the **Blue** Token here to synchronize the Transceivers. Token port is protected by a flexible cap when not in use.

Battery Latch:
Holds battery in place.

LifeSync® Battery:
Battery is removable for charging (in the Monitor Transceiver).

Turn Patient Transceiver ON by inserting a Blue 3/5 Lead LeadWear Connector into the BLUE connector port.

Only use the Blue Token to synchronize Patient Transceiver.

VISUAL STATUS INDICATORS

SETUP			
1	**RETURN TOKEN TO MONITOR TRANSCEIVER**	YELLOW—FLASHING	Return Token to Monitor Transceiver (The Transceiver will BEEP once when Token is fully inserted)
STATUS			
2	**TRANSMITTING ECG - BEDSIDE**	YELLOW - SOLID	No Communication
		GREEN FLASHING	Bedside monitor communication in process
3	**TRANSMITTING ECG - CART**	OFF	No Communication
		YELLOW - SOLID	No Communication
		GREEN FLASHING	Cart communication in process
4	**SERVICE**	RED - SOLID OR FLASHING	Transceiver malfunction - service required
5	**LEAD OFF**	OFF	All leads connected
		YELLOW - SOLID	Check patient leads and electrodes
6	**LOW BATTERY** SWAP BATTERY WITH MONITOR TRANSCEIVER	OFF	Battery has operational charge
		YELLOW - FLASHING	Low charge level - swap battery with Monitor Transceiver

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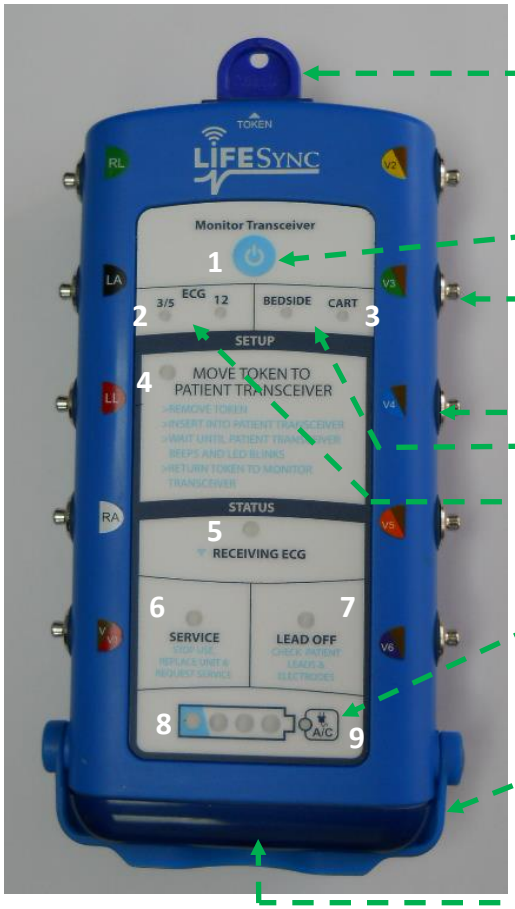
2.1 Monitor Transceiver



LifeSync® Token Port:
Insert the Tokens here; **(BLUE)** to synchronize the Transceivers, **(GREEN)** to select 3/5 lead ECG or 12 lead ECG, and (YELLOW) to set between Bedside and Cart.

Power ON/OFF:
Turn Monitor Transceiver ON with On/Off switch.

ECG Monitor Connections:
Posts for connection to ECG lead wire set.

Bedside/Cart:
Use YELLOW Token to set between Bedside and Cart.

ECG:
Use **GREEN** Token to select 3/5 lead or 12 lead.

Battery Charge and A/C Indicator:
Indicates when connected to A/C and amount of remaining charge on battery.

Battery Latch:
Holds battery in place.

LifeSync® Rechargeable Battery:
Insert removable battery here for charging. A built-in battery charger automatically charges the battery whenever the Monitor Transceiver is connected to the LifeSync® Power Supply plugged into AC power.

VISUAL STATUS INDICATORS

1	**MONITOR TRANSCEIVER POWER ON/OFF SWITCH**	ON/OFF SWITCH	Press to turn unit ON or OFF
2	**GREEN TOKEN**		
	ECG - 3/5	OFF	3/5 lead not selected
		GREEN - SOLID	3/5 lead selected
	ECG - 12	OFF	12 lead not selected
		GREEN - SOLID	12 lead selected
3	**YELLOW TOKEN**		
	BEDSIDE	OFF	Bedside not selected
		GREEN - SOLID	Bedside selected
	CART	OFF	Cart not selected
		GREEN - SOLID	Cart selected

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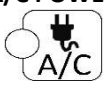
SETUP			
4	**MOVE TOKEN TO PATIENT TRANSCEIVER**	YELLOW - SOLID	
STATUS			
5	**RECEIVING ECG**	YELLOW - SOLID	No Communication
		GREEN - FLASHING	Communication in process - receiving ECG
6	**SERVICE**	RED - SOLID OR FLASHING	Transceiver malfunction - service required
7	**LEAD OFF**	OFF	All leads connected
		YELLOW - SOLID	Check patient leads and electrodes
8	**BATTERY CHARGING AND FUEL GAUGE**	GREEN - SOLID	Battery is fully charged
		GREEN - FLASHING	Battery is charging
		NOTE: The GREEN light only flashes when the unit is connected to the LifeSync® Power Supply plugged into AC power.	
		YELLOW – FLASHING	Battery charge level low, currently operating on battery and less than 60 minutes operation time remains.
		NOTE: The YELLOW light is only active when the unit is NOT connected to the LifeSync® Power Supply plugged into AC power.	
9	**A/C POWER** 	GREEN – SOLID	Indicates when A/C Power is applied

LifeSync® Rechargeable Battery, LS-405

The LifeSync® Rechargeable Battery is a 3.6 Volt rechargeable Lithium-ion battery, and is interchangeable between the LifeSync® Patient Transceiver and the LifeSync® Monitor Transceiver. Batteries are shipped in a partial charge state.

The LifeSync® Battery charges in less than eight hours, when installed in a LifeSync® Monitor Transceiver that is connected to the LifeSync® Power Supply plugged into 110V AC power.

NOTE: If battery is new, remember to remove the plastic tape from the battery contacts before first use. A new battery will need to be charged in a LifeSync® Monitor Transceiver for approximately eight hours before first use.

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A new, fully charged battery will power a LifeSync® Patient Transceiver for a maximum of 16 hours, and a LifeSync® Monitor Transceiver for a maximum of 8 hours. At end-of-life battery capacity will be approximately 80% of original capacity. It is recommended that batteries be discarded after one year of normal use (400 discharge cycles).

LifeSync® Battery Charge Indicator: An easy-to-read gauge on the Monitor Transceiver front panel indicates amount of charge. Each LED represents 25% of battery life. A Low Battery Indicator on the front panel of the Patient Transceiver indicates when less than 60 minutes of operation remain.

Token

The LifeSync® **BLUE** Token is used to establish communication or synchronize the LifeSync® Patient Transceiver and LifeSync® Monitor Transceiver. The **BLUE** Token is not programmed for a particular transceiver; it works by transferring address and communication mode information between two transceivers during the synchronizing process.

NOTE: LifeSync® Monitor Transceiver will not operate without **BLUE** Token. **BLUE** Token should remain in Token port of the LifeSync® Monitor Transceiver at all times, except when it is being used to synchronize a LifeSync® Patient Transceiver.

Configuration Tokens

The LifeSync® Monitor Transceiver can be switched from 5 Lead to 12 Lead ECG Mode using the **GREEN** Token and from Bedside Permanent Monitoring to Cart Temporary Monitoring using the **YELLOW** Token.

NOTE: Configuration changes are not part of normal operation and should only be performed by trained individuals. See Wireless System Setup for a full description of the procedure.

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Power Supply, LS-132

The LifeSync® Power Supply converts AC power to the 5.5 V DC power required to operate the LifeSync® Monitor Transceiver and charge the LifeSync® Rechargeable Battery.

Note: When the LifeSync® Monitor Transceiver is disconnected from the LifeSync® Power Supply or AC power, the battery will stop charging and LifeSync® Monitor Transceiver will be powered by the rechargeable battery.

Accessories

Telemetry Pouch

A Telemetry Pouch (LS-213) may be used to protect the LifeSync® Patient Transceiver from fluids and other hazardous materials.

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Introduction to LifeSync® Patient Cables and Cable Adapters

Patient Cables and Cable Adapters

The LifeSync® Patient Cables and Cable Adapters provide an interface between the ECG equipment and LifeSync® LeadWear® Disposables. The LifeSync® Patient Cables and Cable Adapters permit the use of LeadWear® Disposables with ECG monitoring equipment via direct electrical connection.

Contact your Sales Representative or Customer Service for a current list of Cable Adapters available.

NOTE: LifeSync® Patient Cables and Cable Adapters are connected directly to the monitor or trunk cable of 5 or 12 lead ECG monitors as well as directly connected to wireless telemetry transmitters.

NOTE: LifeSync® Patient Cables and Cable Adapters are non-sterile, reusable and latex free.

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LifeSync® Wireless System Operation

The LifeSync® Wireless System works with existing ECG monitor equipment.

NOTE: Proper function of the LifeSync® Wireless System with the ECG monitoring equipment should be confirmed before use with a patient.
(See System Functional Check on page 39 of this Manual.)

Wireless System Set Up

Install/Check Batteries in Transceivers

NOTE: If battery is new, remember to remove the plastic tape from the battery contacts before first use. A new battery will need to be charged in a LifeSync® Monitor Transceiver for approximately eight hours before first use.

1. Check battery charge level by installing each battery into a Monitor Transceiver connected to A/C power. If all four battery indicators are not lit, allow the battery to fully charge or replace battery with a fully charged battery. Each LED represents 25% of battery life.
2. Release the battery latch by pushing the latch thumb hold toward the back of the transceiver. Remove battery from each transceiver.
3. Re-install battery into each transceiver and secure by pulling the latch thumb hold toward the front of the transceiver until it snaps securely into place.

NOTE: Use a fully charged battery. To charge the LifeSync® Rechargeable Battery ensure the LifeSync® Monitor Transceiver is connected to the LifeSync® Power Supply and plugged to AC power and the battery is fully inserted and latched

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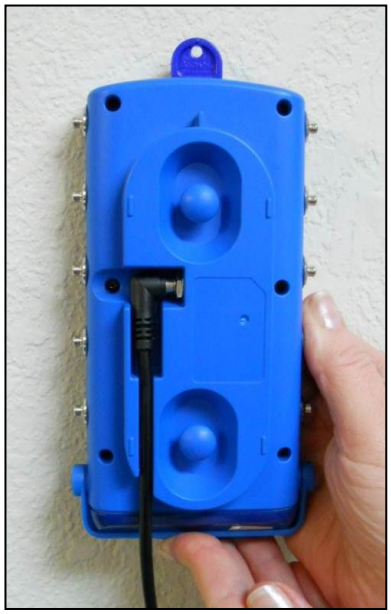
Mount the LifeSync® 2.1 Monitor Transceiver

1. Connect LifeSync® Monitor Transceiver to LifeSync® Power Supply and AC power source. (The Monitor Transceiver can be used with a fully charged battery without the Power Supply when installed on a transport monitor or ECG cart)

2. Secure the LifeSync® Mounting Plate to the desired location, using the supplied double-sided adhesive tape (or other method). The LifeSync® Mounting Plate is pre-drilled for attachment to a variety of third party mounting solutions, including the GCX series of pole and rail mounts (not supplied by LifeSync®)



NOTE: The arrow on the LifeSync® Mounting Plate must be pointing upward.

3. Insert buttons on back of LifeSync® Monitor Transceiver into slots on LifeSync® mounting plate, and slide transceiver unit downward until it clicks into place.

4. Connect leads of the standard ECG lead wire set from the ECG equipment to the corresponding snap attachments on the LifeSync® Monitor Transceiver, matching lead marking and color codes.

5. Ensure a LifeSync® **BLUE** Token is seated in the Token port on Monitor Transceiver.

NOTE: LifeSync® Monitor Transceiver will not operate without LifeSync® **BLUE** Token. **BLUE** Token should remain in token port of the LifeSync® Monitor Transceiver at all times, except when it is being used to synchronize a LifeSync® Patient Transceiver.

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Configuration of the LifeSync® 2.1 Monitor Transceiver for 5 or 12-Lead Operation

1. Connect LifeSync® Monitor Transceiver to LifeSync® Power Supply and AC power source.
2. Power up Monitor Transceiver by depressing On/Off switch.
3. Current 5 or 12 ECG mode will be illuminated.
4. To change ECG mode configuration, remove the synchronization **BLUE** Token from the slot on the Monitor Transceiver.
5. Insert the **GREEN** Configuration Token into the Token slot.
6. The Monitor Transceiver will BEEP 4 times, and illuminate the new ECG mode.
7. Remove the **GREEN** configuration Token and replace with the **BLUE** synchronization Token.

NOTE: LifeSync® Monitor Transceiver will remember the current pairing and there is no need to re-synchronize with the LifeSync® Patient Transceiver when changing the ECG configuration.

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Configuration of the LifeSync® 2.1 Monitor Transceiver for Bedside or Cart Operation

1. Connect LifeSync® Monitor Transceiver to LifeSync® Power Supply and AC power source.
2. Power up Monitor Transceiver by depressing On/Off switch.
3. Current BEDSIDE (permanent monitoring) or CART (temporary monitoring) will be illuminated.
4. To change BEDSIDE/CART configuration, remove the synchronization **BLUE** Token from the slot on the Monitor Transceiver.
5. Insert the **YELLOW** Configuration Token into the Token slot.
8. The Monitor Transceiver will BEEP 4 times, and illuminate the new configuration.
9. Remove the **YELLOW** configuration Token and replace with the **BLUE** synchronization token.

NOTE: LifeSync® Monitor Transceiver will need to re-synchronize with the LifeSync® Patient Transceiver when changing the BEDSIDE/CART configuration.

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User Instructions: Wireless Monitoring

5 Lead Wireless Monitoring

To continuously monitor 3 lead or 5 lead ECG signals using a cardiac monitor.

Confirm LifeSync® Monitor Transceiver Settings

NOTE: Make sure a LifeSync® **BLUE** Token is installed in the token port of the Monitor Transceiver.

1. Press Power On/Off switch to turn Monitor Transceiver ON.
2. Confirm the indicator "5 LEAD" is illuminated.
3. Confirm the "BEDSIDE" is illuminated.

Apply LifeSync® LeadWear® Disposable

1. Select appropriate size 5 Lead LeadWear® Disposable (BLUE connector) for the patient (refer to size chart on page 10).

NOTE: For placement of LeadWear® Disposable on patient, refer to "User Instructions: LeadWear® Disposable for 5 Lead Monitoring", on page 33 of this Manual.

2. Insert BLUE 5 Lead LeadWear® Connector into BLUE slot on LifeSync® Patient Transceiver. This will turn the LifeSync® Patient Transceiver ON. Ensure that connector is seated securely and that tabs lock into place.

3. The LifeSync® Patient Transceiver may be placed inside Telemetry Pouch. Pouch can be placed on or near the patient.

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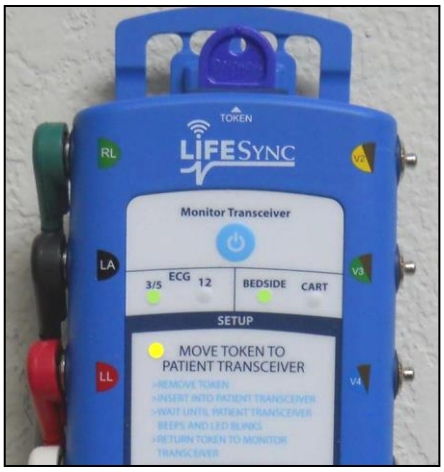
Synchronize LifeSync® Transceivers



1. Follow instructions in SETUP section of Monitor Transceiver.

2. REMOVE TOKEN – Remove **BLUE** Token, the "MOVE TOKEN TO PATIENT TRANSCEIVER" indicator will glow SOLID YELLOW.

3. INSERT INTO PATIENT TRANSCEIVER – Pull the flexible cap away from the token port on Patient Transceiver and fully insert **BLUE** Token into token port.

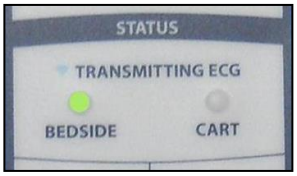
4. WAIT UNTIL PATIENT TRANSCEIVER BEEPS AND LED BLINKS – A single audible BEEP is produced when BLUE Token is fully inserted and "RETURN TOKEN INTO MONITOR TRANSCEIVER" indicator on the Patient Transceiver will glow FLASHING YELLOW.

5. RETURN TOKEN TO MONITOR TRANSCEIVER – Remove **BLUE** token from Patient Transceiver and close flexible cap over token port; the "RETURN TOKEN INTO MONITOR TRANSCEIVER" indicator on the Patient Transceiver will go off.

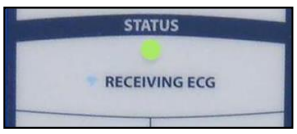
6. Fully insert the **BLUE** Token into the token port on the Monitor Transceiver. The Monitor Transceiver will BEEP when the token is properly re-inserted and the "MOVE TOKEN TO PATIENT TRANSCEIVER" indicator will go off.

7. Within a few seconds, the Transceivers' STATUS indicators will display FLASHING GREEN if communicating or SOLID YELLOW if communication failed. If communication fails repeat steps 1 thru 5.

Patient Transceiver
STATUS - TRANSMITTING ECG BEDSIDE indicator will flash GREEN; Communication in process with Monitor Transceiver



Monitor Transceiver
STATUS - RECEIVING ECG indicator will flash GREEN; Communication in process with Patient Transceiver



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The patient's ECG signal will appear on the cardiac monitor within a few seconds. If ECG cardiac monitor is respiration capable the respiration signal will also appear.

12 Lead Wireless Monitoring

To continuously monitor 12 lead ECG signals using a 12 lead cardiac monitor.

Confirm LifeSync® Monitor Transceiver Settings

NOTE: Make sure a LifeSync® **BLUE** Token is installed in the token port of the Monitor Transceiver.

1. Press Power On/Off switch to turn Monitor Transceiver ON.
2. Confirm the indicator "12 LEAD" is illuminated.
3. Confirm the "BEDSIDE" is illuminated.

Apply LifeSync® LeadWear® Disposable

1. Select appropriate size 5 Lead LeadWear® Disposable (BLUE connector) for the patient (refer to size chart on page 10) and Precordial LeadWear® Disposable (GREEN connector).

NOTE: For placement of LeadWear® Disposable on patient, refer to "User Instructions: LeadWear® Disposable for 12 Lead Monitoring", on page 35 of this Manual.

2. Insert both BLUE 5 Lead LeadWear® and GREEN precordial LeadWear® Connectors into BLUE and GREEN slots on Patient Transceiver, matching colors. Inserting the Lead LeadWear® (BLUE) Connector will turn the Patient Transceiver ON. Ensure that connectors are seated securely and that tabs lock into place.

3. Place LifeSync® Patient Transceiver inside Telemetry Pouch. Pouch can be placed on or near the patient.

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Synchronize LifeSync® Transceivers

1. Follow instructions in SETUP section of Monitor Transceiver.

2. REMOVE TOKEN – Remove **BLUE** Token, the "MOVE TOKEN TO PATIENT TRANSCEIVER" indicator will glow SOLID YELLOW.

3. INSERT INTO PATIENT TRANSCEIVER – Pull the flexible cap away from the token port on Patient Transceiver and fully insert **BLUE** Token into token port.

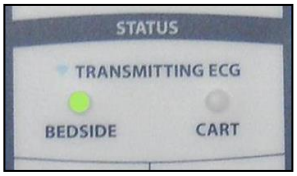
4. WAIT UNTIL PATIENT TRANSCEIVER BEEPS AND LED BLINKS – A single audible BEEP is produced when BLUE Token is fully inserted and "RETURN TOKEN INTO MONITOR TRANSCEIVER" indicator on the Patient Transceiver will glow FLASHING YELLOW.

5. RETURN TOKEN TO MONITOR TRANSCEIVER – Remove **BLUE** token from Patient Transceiver and close flexible cap over token port; the "RETURN TOKEN INTO MONITOR TRANSCEIVER" indicator on the Patient Transceiver will go off.

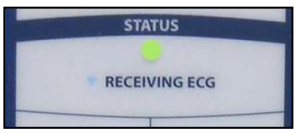
6. Fully insert the **BLUE** Token into the token port on the Monitor Transceiver. The Monitor Transceiver will BEEP when the token is properly re-inserted and the "MOVE TOKEN TO PATIENT TRANSCEIVER" indicator will go off.

7. Within a few seconds, the Transceivers' STATUS indicators will display FLASHING GREEN if communicating or SOLID YELLOW if communication failed. If communication fails repeat steps 1 thru 5.

Patient Transceiver
STATUS - TRANSMITTING ECG BEDSIDE indicator will flash GREEN; Communication in process with Monitor Transceiver



Monitor Transceiver
STATUS - RECEIVING ECG indicator will flash GREEN; Communication in process with Patient Transceiver



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The patient's ECG signal will appear on the 12 lead ECG monitor within a few seconds. If ECG cardiac monitor is respiration capable the respiration signal will also appear.

Cart ECG

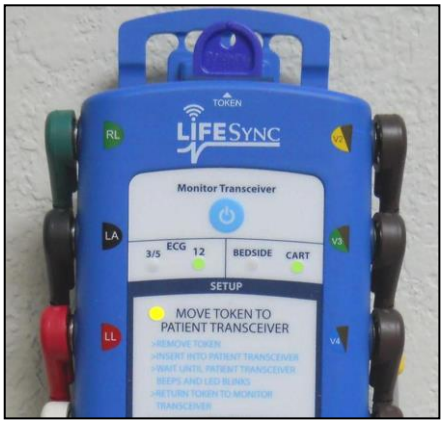
Cart mode allows a single Patient Transceiver to communicate with two Monitor Transceivers simultaneously to monitor 5 lead or 12 lead ECG signal.

NOTE: This procedure requires a secondary LifeSync® Monitor Transceiver configured in Cart mode to be set up on a second ECG device.

Confirm LifeSync® Monitor Transceiver Settings

NOTE: Make sure a LifeSync® **BLUE** Token is installed in the token port of both Monitor Transceivers.
Do not change any settings on the BEDSIDE Monitor Transceiver. The BEDSIDE Monitor Transceiver is the unit that is already synchronized with the Patient Transceiver.

1. Press Power On/Off switch to turn CART Monitor Transceiver ON.
2. Confirm the indicator "5 LEAD" or "12 LEAD" is illuminated.
3. Confirm the "CART" is illuminated.



Cart 12 Lead ECG Only - Apply Precordial LeadWear® Disposable

1. Select Precordial LeadWear® Disposable (GREEN connector).

NOTE: For placement of Precordial LeadWear® Disposable on patient, refer to "User Instructions: LeadWear® Disposable for 12 Lead Monitoring", on page 35 of this Manual.

2. Ensure the V (BROWN) lead of the 5 Lead LeadWear® Disposable (already on the patient) is in V1 location.

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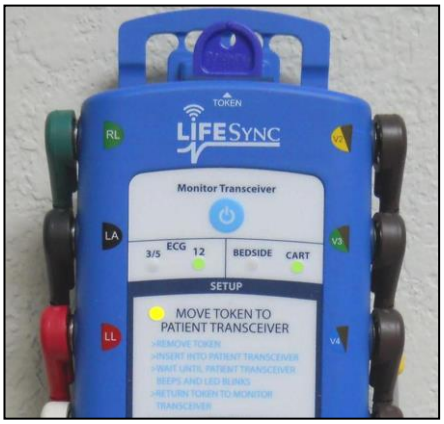
3. Insert GREEN precordial LeadWear® Connector into GREEN slot on Patient Transceiver. Ensure that connector is seated securely and that tabs lock into place.

Synchronize LifeSync® Transceivers



1. Follow instructions in SETUP section of CART Monitor Transceiver.

2. REMOVE TOKEN – Remove **BLUE** Token, the "MOVE TOKEN TO PATIENT TRANSCEIVER" indicator will glow SOLID YELLOW.

3. INSERT INTO PATIENT TRANSCEIVER – Pull the flexible cap away from the token port on Patient Transceiver and fully insert **BLUE** Token into token port.

4. WAIT UNTIL PATIENT TRANSCEIVER BEEPS AND LED BLINKS – A single audible BEEP is produced when BLUE Token is fully inserted and "RETURN TOKEN INTO MONITOR TRANSCEIVER" indicator on the Patient Transceiver will glow FLASHING YELLOW.

5. RETURN TOKEN TO MONITOR TRANSCEIVER – Remove **BLUE** token from Patient Transceiver and close flexible cap over token port; the "RETURN TOKEN INTO MONITOR TRANSCEIVER" indicator on the Patient Transceiver will go off.

6. Fully insert the **BLUE** Token into the token port on the CART Monitor Transceiver. The CART Monitor Transceiver will BEEP when the token is properly re-inserted and the "MOVE TOKEN TO PATIENT TRANSCEIVER" indicator will go off.

7. Within a few seconds, the Transceivers' STATUS indicators will display FLASHING GREEN if communicating or SOLID YELLOW if communication failed. If communication fails repeat steps 1 thru 5.

Patient Transceiver
STATUS - TRANSMITTING ECG CART indicator and BESIDE indicator will both flash GREEN;

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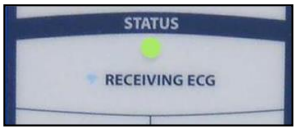
Communication in process with both BEDSIDE Monitor Transceiver and CART Monitor Transceiver.

CART Monitor Transceiver
STATUS - RECEIVING ECG indicator will flash GREEN; Communication in process with Patient Transceiver.



The patient's ECG signal will appear on both BESIDE ECG monitor and CART ECG monitor within a few seconds. If CART ECG cardiac monitor is respiration capable the respiration signal will also appear.

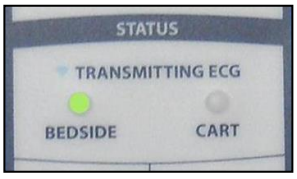
NOTE: Cart and Bedside communication modes are independent and can be run without the other.

8. The Patient Transceiver will communicate with the CART Monitor Transceiver for two minutes.

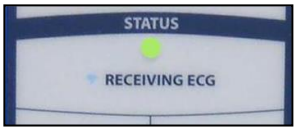
9. After two minutes, the Patient Transceiver will automatically end communication with the CART Monitor Transceiver.

   The Transceiver indicators will reflect the change in communication status:

   Patient Transceiver
   STATUS - TRANSMITTING ECG BEDSIDE indicator will flash GREEN; Communication in process with BEDSIDE Monitor Transceiver. STATUS - TRANSMITTING ECG CART will go off.



   BEDSIDE Monitor Transceiver
   STATUS - RECEIVING ECG indicator will flash GREEN; Communication in process with Patient Transceiver.



   CART Monitor Transceiver
   STATUS - RECEIVING ECG indicator will flash YELLOW; No Communication.

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Cart 12 Lead ECG Only – Remove Precordial LeadWear® Disposable

1. Disconnect the GREEN Connector from the Patient Transceiver. The Precordial LeadWear® Disposable may now be removed from the patient, or may be left in place for a future use. If necessary, move the V (BROWN) lead of the 5 Lead LeadWear® Disposable to desired V lead location.

NOTE: Place ECG lead electrode on V (BROWN) lead before moving on patient.

Patient Transfer: Wireless to Wireless

To permanently transfer a patient from one monitor to another monitor.

NOTE: This requires an extra LifeSync® Monitor Transceiver - ECG device set up.

Confirm Transceiver Settings

NOTE: Make sure a LifeSync® Token is installed in the token port of both Monitor Transceivers.

1. Press Power On/Off switch to turn the extra Monitor Transceiver ON. This is the transceiver attached to the monitor that the patient is being transferred to and will become the primary Monitor
2. Confirm the indicator "5 LEAD" or "12 LEAD" is illuminated.
3. Confirm the "BEDSIDE" is illuminated.

Synchronize LifeSync® Transceivers

1. Follow instructions in SETUP section of extra Monitor Transceiver.
   a. Remove Token
   b. Insert into Patient Transceiver
   c. Wait until Patient Transceiver beeps and LED blinks
   d. RETURN TOKEN TO MONITOR TRANSCEIVER

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NOTE: Step by step instructions for 5 LEAD wireless monitoring are found on page 22. Step by step instructions for 12 LEAD wireless monitoring are found on page 24.

System Removal

1. Leave the Monitor Transceiver attached to the side of the patient monitor until its next use. The Monitor Transceiver can be left on unless it will not be used for an extended period of time.
   To turn the Monitor Transceiver OFF, Press Power On/Off switch.
2. Remove Patient Transceiver Telemetry Pouch. To remove LeadWear® connectors from Transceiver, squeeze clips on LeadWear® connector and pull straight out from Transceiver.
3. Gently remove LeadWear® Disposable and electrodes from patient.
4. Discard LeadWear® Disposable, electrodes and Telemetry Pouch.
5. Store Patient Transceiver in a designated storage location.

NOTE: If system is not to be used for an extended period, the batteries should be removed from the Patient Transceiver and the Monitor Transceiver, and stored separately.

LifeSync® Rechargeable Batteries

The Monitor Transceiver should be connected to the Power Supply and plugged to AC power at all times, in order to ensure the battery is fully charged. When the battery in the Patient Transceiver runs low, it can quickly be exchanged for a fully charged battery in the Monitor Transceiver.

NOTE: Each Transceiver has a Battery Charge Indicator that flashes YELLOW when its battery is running low, accompanied by a periodic BEEP. Replace the low battery with a fully-charged battery within 60 minutes to maintain Transceiver operation.

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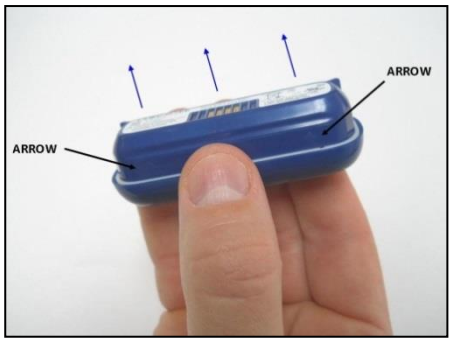
WARNING: Battery capacity will change over the life of the battery. A fully charged unit does not mean that the battery is capable of running the Patient Transceiver. If battery is more than one year old, it is recommended that the battery be replaced.

Exchanging Batteries

First remove the charged battery from the Monitor Transceivers by releasing the battery latch and sliding the battery out of the battery slot.

Exchange charged battery from Monitor Transceiver with battery in Patient Transceiver.

Insert the replacement battery with contacts facing the transceiver body, and arrows on the battery facing up when viewing the front of the Transceiver. Secure battery latch.



Insert battery from Patient Transceiver into the Monitor Transceiver for charging.

NOTE: Exchanging batteries does not require re-synchronization of Transceivers.

Charging Batteries

When the Monitor Transceiver is connected to the Power Supply and plugged to AC power, it functions as a charger for the battery. The battery reaches full charge in less than eight hours.

NOTE: At end-of-life battery capacity will be approximately 80% of original capacity. It is recommended that batteries be discarded after one year of normal use (400 discharge cycles)

CAUTION: Use only a LifeSync® Monitor Transceiver to recharge the battery.

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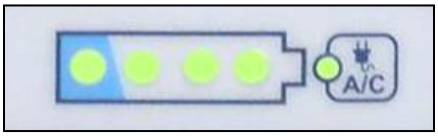
Monitor Transceiver Battery Charging Indicator



The Battery Charging indicator on the front of the Monitor Transceiver displays a GREEN FLASHING light when the battery charger function is active. As the battery is charged or discharged the number of LEDs illuminated increases or decreases. Each LED represents 25% of battery capacity.

When the Monitor Transceiver is not connected to the Power Supply and plugged to AC power and is being powered by a rechargeable battery, the battery charger function is inactive and the Battery Charging indicator will not be lit, and the gauge will indicate the remaining battery available.

When the Monitor Transceiver is connected to the Power Supply and plugged to AC power and has a less-than-fully-charged rechargeable battery installed, the Battery Charging indicator will flash GREEN, to indicate that the battery is charging. It will take up to eight hours for the Monitor Transceiver to finish charging a discharged battery. The Battery Charging indicator will glow SOLID GREEN for all LEDs when charging is complete.

Battery Storage

The battery should be removed from the Patient Transceiver and stored separately when not in use for more than a few days. (See more information about battery storage in the Maintenance and Troubleshooting section, on page 50 of this Manual.)

CAUTION:

- Store rechargeable batteries between 10°C and 26°C/ 50°F and 80°F.
- Store rechargeable batteries away from direct sunlight in a low humidity location with little temperature variation.
- Discard rechargeable batteries according to national, state and local regulations.

Respiration

If the Monitor Transceiver is being used with a patient monitor that is equipped to display patient respiration via thoracic impedance pneumography, the patient monitor will continue to display patient respiration as long as the patient monitor is configured to derive respiration from Lead I (LL-LA) or Lead II (LL-RA). Consult ECG equipment manual for more information about proper settings and operation of the respiration function. Also, refer to the Specifications section on page 58 of this manual for details on LifeSync® Wireless System respiration function.

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User Instructions: LeadWear® Disposable

5 Lead Monitoring

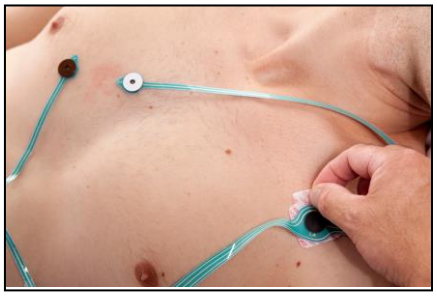
1. Remove LeadWear® Disposable from package.

NOTE: Release LeadWear® Disposable from the package insert card with care, by pressing on the colored side of each snap. DO NOT pull snaps out of holes by tugging on the LeadWear® Disposable itself.

2. Attach electrodes to all snaps on the LeadWear® Disposable, and place on the patient as indicated in the diagram and table below.

NOTE: Follow electrode manufacturer's guidelines for skin prep prior to placing electrodes on patient.

NOTE: Place electrode LA on the left shoulder first. See chart for remaining electrode placements.



5 Lead LeadWear® Disposable Electrode Placement		
LA	Black	Left shoulder
RA	White	Right shoulder
LL	Red	Left-side of chest below navel
RL	Green	Left-side of chest just above LL
V	Brown	Center of chest (desired location)

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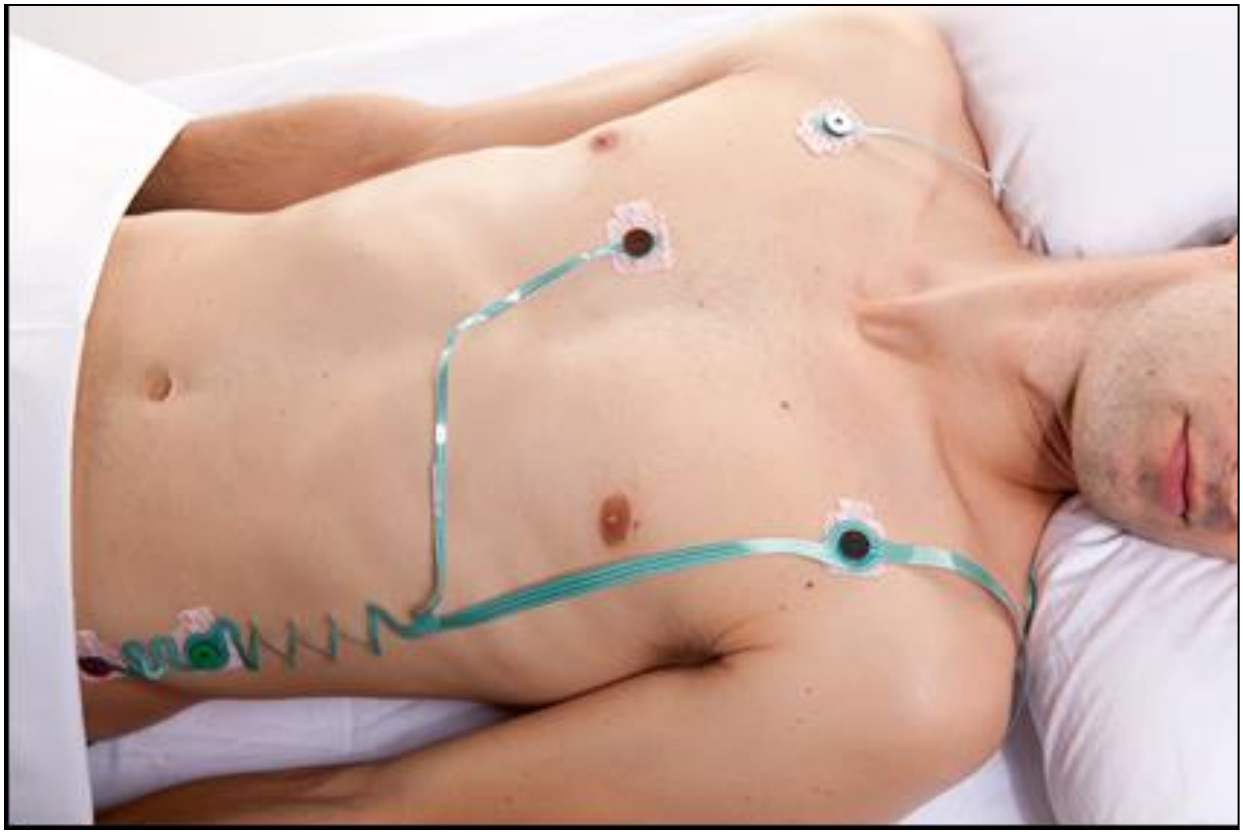

NOTE: The position of the RL (Right Leg) electrode with the LifeSync® LeadWear® Disposable is different from standard ECG lead placement.

NOTE: Confirm the fit of LeadWear® Disposable on patient. If lead placements don't reach or there is too much slack, select a different size.

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12 Lead Monitoring

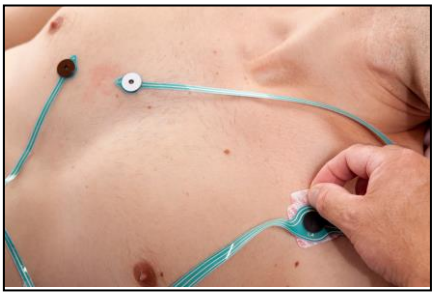
1. Remove LeadWear® Disposable from package(s).

NOTE: Release LeadWear® Disposable from the package insert card with care, by pressing on the colored side of each snap. DO NOT pull snaps out of holes by tugging on the LeadWear® Disposable itself.

2. Attach electrodes to all snaps on 5 Lead LeadWear® Disposable, and place on the patient as indicated in the diagrams and tables below.

NOTE: Follow electrode manufacturer's guidelines for skin prep prior to placing electrodes on patient.

NOTE: Place electrode LA on the left shoulder first. See chart for remaining electrode placements.



5 Lead LeadWear® Disposable Electrode Placement		
LA	Black	Left shoulder
RA	White	Right shoulder
LL	Red	Left-side of chest below navel
RL	Green	Left-side of chest just above LL
V	Brown	Fourth intercostal space at right sternal border (V1 position)

NOTE: Place electrode V2 first. See chart for remaining electrode placements.

Precordial LeadWear® Disposable Electrode Placement		
V2	Yellow	Fourth intercostal space at left sternal border
V3	Green	Midway between V2 and V4
V4	Blue	Fifth intercostal space midclavicular line
V5	Orange	At horizontal level of V4 left anterior axillary line
V6	Violet	At horizontal level of V4 left midaxillary line

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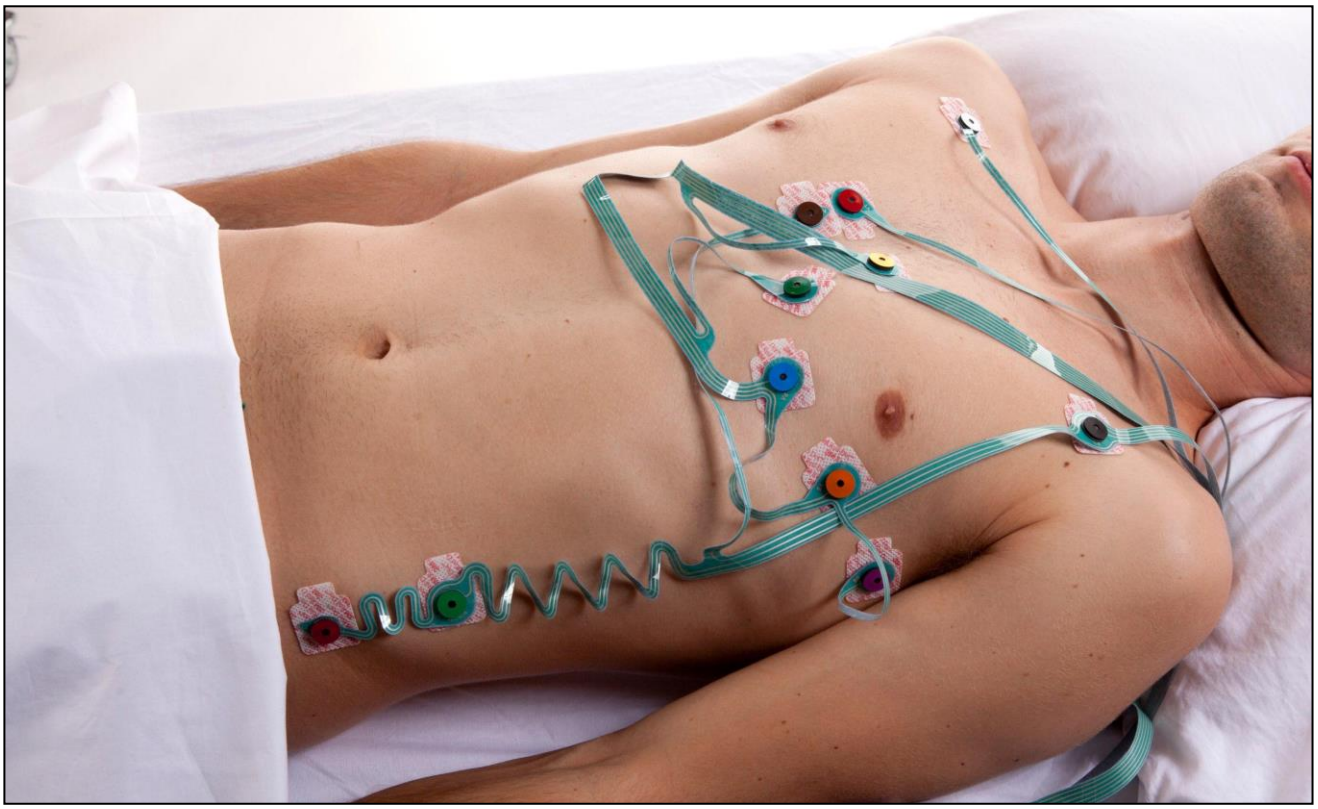
NOTE: Although the V1 lead on the Precordial LeadWear® Disposable is not used for 12 lead operation, it should be fastened to the patient's chest in order to avoid accidental pulling of the LeadWear® Disposable.

NOTE: The position of the RL (Right Leg) electrode with the LeadWear® Disposable is different from standard ECG lead placement.

NOTE: Confirm the fit of LeadWear® Disposable on patient. If lead placements don't reach or there is too much slack, select a different size.



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LifeSync® Patient Cables and Cable Adapters Operation

User Instructions: Patient Cables and Cable Adapters

12 Lead Patient Cables and Cable Adapters

To use LeadWear® Disposable directly with 12 Lead ECG monitoring equipment.

1. Select appropriate size 5 Lead LeadWear® Disposable (BLUE connector) and precordial LeadWear® Disposable (GREEN connector) for the patient (refer to size chart on page 10).

NOTE: For placement of LeadWear® Disposable on patient, refer to "User Instructions: LeadWear® Disposable for 12 Lead Monitoring", on page 35 of this Manual. Ensure the monitor is set for 12 Lead monitoring.

2. Connect Patient Cable or Cable Adapter to the trunk cable or monitoring equipment.
3. Connect the LeadWear® Disposables (BLUE and GREEN connector) to the Patient Cable or Cable Adapter

5 Lead Patient Cables and Cable Adapters

To use LeadWear® Disposable directly with ECG monitoring equipment.

1. Select appropriate size 5 Lead LeadWear® Disposable (BLUE connector) for the patient (refer to size chart on page 10).

NOTE: For placement of LeadWear® Disposable on patient, refer to "User Instructions: LeadWear® Disposable for 5 Lead Monitoring", on page 33 of this Manual.

2. Connect Patient Cable or Cable Adapter to the trunk cable or monitoring equipment.

3. Connect the LeadWear® Disposable (BLUE connector) to the Patient Cable or Cable Adapter.

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Patient Transfer: Wireless to Patient Cables and Cable Adapters

To permanently transfer a patient from wireless monitoring to a wired connection.

1. Connect Patient Cable or Cable Adapter to the trunk cable or monitoring equipment.
2. Remove LeadWear® Disposable from the LifeSync® Patient Transceiver, by squeezing clips on LeadWear® Connector(s) and pulling straight out from transceiver.
3. Connect LeadWear® Disposable (BLUE connector 5 Lead or GREEN connector 12 Lead) to the Patient Cable or Cable Adapter.

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Maintenance & Troubleshooting

System Functional Check

The LifeSync® Wireless System requires neither technical maintenance nor calibration.

It is recommended that the following procedure be used to confirm the proper function of system components before initial use, and at regularly scheduled intervals, as dictated by the institution's plan for equipment performance confirmation.

Required Equipment

Two LifeSync® Monitor Transceivers
One LifeSync® Patient Transceiver
LifeSync® LeadWear® Disposable
ECG/RESP 12 Lead Patient Simulator
Two LifeSync® System Compatible ECG Monitors:
- One 5 lead Bedside Monitor (including trunk cable and lead wires)
- One 12 lead ECG Machine (including trunk cable and lead wires)

NOTE: The LifeSync® System performance has been confirmed with a variety of commonly used ECG equipment. Contact LifeSync Corporation Customer Service at 866-ECG-3888 for information on ECG monitors that are compatible with the LifeSync® System.

A. Battery Preparation

NOTE: Batteries are shipped in a partially charged state, with a plastic film cover covering the contacts. This film must be removed prior to use.

1. Remove the plastic film cover from the battery contacts.
2. Leave one battery uncharged. Charge a second battery to the fully charged state. Partially charge a third battery, to the point that only one LED is lit on the Monitor Transceiver battery charge indicator.

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B. Monitor Transceiver Set Up/Power on Test/Battery Charger

1. Insert blue Token into Token port on the top of the Bedside Monitor Transceiver.
2. Place the uncharged battery in this Monitor Transceiver, confirming that the plastic film contact cover has been removed.
3. Connect Monitor Transceiver to the Power Supply and plug to AC Power.
4. Press Power On/Off switch. Confirm that all indicators light for approximately one second and an audible BEEP is heard, this is a user interface test. Confirm that the GREEN Battery Charging indicator is flashing.
5. Confirm the indicator shows ECG 5 Lead mode.
6. Confirm the indicator shows Bedside Communication Mode.
7. Connect lead wires from the cardiac monitor to the Monitor Transceiver, matching colors and lead markings.

C. Patient Transceiver Set Up /Power on Test

1. Insert the fully charged battery into the Patient Transceiver.
2. Remove 5 Lead LeadWear® Disposable from package. Insert 5 Lead LeadWear® Connector into connector port, matching connector colors and connector keys.
3. Confirm that all indicators light for approximately one second and an audible BEEP is heard, this is a user interface test. Confirm that the Low Battery Charge indicator is OFF.
4. Connect electrode snaps on 5 LeadWear® Disposable to Patient Simulator.

D. Transceiver Synchronizing – Single Bedside

1. Remove blue Token from the Bedside Monitor Transceiver. Confirm "Insert Token Into Patient Transceiver" Status indicator on Monitor Transceiver glows SOLID YELLOW.
2. Insert Token into Token port on the side of Patient Transceiver. Wait for Return Token To Monitor Transceiver Status indicator on Patient Transceiver to FLASH YELLOW. Confirm that Patient Transceiver produces a single BEEP when Token is fully seated.
3. Remove Token from Patient Transceiver. Confirm that Return Token To Monitor Transceiver Status indicator goes OFF.
4. Place Token back into Token port of the Bedside Monitor Transceiver. Confirm that the Monitor Transceiver produces a single BEEP, and that the "Insert Token Into Patient Transceiver" Status indicator goes OFF. Confirm that Communication Status indicators on both Transceivers flash GREEN (over "Bedside" on the Patient Transceiver). Confirm that the ECG/Respiration signals appear on the cardiac monitor display, and that the ECG/Respiration signals agree with the ECG Patient Simulator settings.

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E. Monitor Transceiver Set Up – Cart 12 Lead

1. Insert blue Token into Token port on the top of the ECG machine Monitor Transceiver.
2. Place the third partially charged battery in the ECG machine Monitor Transceiver, confirming that the plastic film contact cover has been removed.
3. Press Power On/Off switch. Confirm that all indicators light for approximately one second and an audible BEEP is heard, this is a user interface test. Confirm that the YELLOW Low Battery Charge indicator is flashing and that an audible tone continues to beep.
4. Connect the ECG machine Monitor Transceiver to the Power Supply and plug to AC Power.
5. Confirm the ECG Mode indicator shows ECG 12 Lead mode.
6. Confirm the Communication Mode indicator shows Cart Communication Mode.
7. Connect lead wires from the 12 lead ECG machine to the ECG machine Monitor Transceiver, matching colors and lead markings.
8. Remove Precordial LeadWear® Disposable from package and connect electrode snaps on Precordial LeadWear® Disposable to Patient Simulator (do not connect V1-RED lead).
9. Insert Precordial LeadWear® connector into GREEN connector port. Leave 5 Lead LeadWear® Connector in place.

F. Transceiver Synchronizing – Cart 12 Lead

1. Remove blue Token from the ECG machine Monitor Transceiver. Confirm "Insert Token Into Patient Transceiver" Status indicator on this Monitor Transceiver glows SOLID YELLOW.
2. Insert Token into Token port on the side of Patient Transceiver. Wait for Return Token To Monitor Transceiver Status indicator on Patient Transceiver to FLASH YELLOW. Confirm that Patient Transceiver produces a single BEEP when the Token is fully seated.
3. Remove Token from Patient Transceiver. Confirm that Return Token To Monitor Transceiver Status indicator goes OFF.
4. Place Token back into Token port of the ECG machine Monitor Transceiver. Confirm that the Monitor Transceiver produces a single BEEP, and that the "Insert Token Into Patient Transceiver" Status indicator goes OFF. Confirm that Communication Status indicators on all three transceivers flash GREEN (both "Bedside" and "Cart" on the Patient Transceiver). Confirm that the proper ECG signals appear on both ECG equipment displays, and that the ECG signals agree with the ECG Patient Simulator settings.
5. Wait for two minutes. After two minutes, the Cart ECG machine Monitor Transceiver stops receiving signals from the Patient Transceiver. Confirm that the Communication Status indicator on the Cart ECG machine Monitor Transceiver SOLID YELLOW, the Communication Status indicator on the cardiac Monitor Transceiver flashes GREEN, and only the "Bedside" Communication Status indicator on the Patient Transceiver flashes GREEN.

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G. Transceivers – Confirm Low Battery Charge Indicators on Patient Transceiver

1. Disconnect Monitor Transceivers from ECG equipment and turn equipment OFF.
2. Remove the batteries from all Transceivers. Disconnect the Monitor Transceivers from the Power Supply and plug to AC power.
3. Place the partially charged battery in the Patient Transceiver. Confirm that the Low Battery Charge indicator flashes YELLOW and an audible tone continues to beep. Remove the LeadWear® connector to turn Patient Transceiver OFF.
4. Place the fully charged battery in one Monitor Transceiver. Turn the Transceiver ON and confirm that all Low Battery Charge and Battery Charging indicators are OFF. Repeat with the other Monitor Transceiver.
5. Place the fully charged battery back into the Patient Transceiver.
6. Connect both Monitor Transceivers to the Power Supplies and plug to AC power. Confirm that the GREEN Battery Charge indicator is flashing. Let batteries charge for 8 hours before use.

System Configuration and Functional Check

The LifeSync® Wireless System is designed for configuration by a Biomed or other trained individual. The absence of switches and configuration options allows for simple operation by the healthcare provider without an understanding of the different configuration modes supported. The following procedure guides the Biomed through a full system test, including functional tests of all possible configurations, and verifying all settings are working.

A. Battery Preparation

NOTE: Batteries are shipped in a partially charged state, with a plastic film cover covering the contacts. This film must be removed prior to use.

1. Remove the plastic film cover from the battery contacts.
2. Leave one battery uncharged. Charge a second battery to the fully charged state. Partially charge a third battery, to the point that only one LED is lit on the Monitor Transceiver battery charge indicator.

B. Monitor Transceiver Set Up/Power on Test/Battery Charger

1. Insert blue Token into Token port on the top of the Bedside Monitor Transceiver.
2. Place the uncharged battery in this Monitor Transceiver, confirming that the plastic film contact cover has been removed.
3. Connect Monitor Transceiver to the Power Supply and plug to AC Power.

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4. Press Power On/Off switch. Confirm that all indicators light for approximately one second and an audible BEEP is heard, this is a user interface test. Confirm that the GREEN Battery Charging indicator is flashing.
5. Insert the green configuration Token marked ECG in the Token port on the top of the Monitor Transceiver. The Monitor Transceiver will BEEP 4 times, and change the ECG mode, which will be illuminated on the front panel. Confirm that the configuration function is working by performing this operation several times. Select ECG 5 Lead mode.
6. Insert the yellow configuration Token Marked Bedside/Cart into the Token Port on the top of the Monitor Transceiver. The Monitor Transceiver will BEEP 4 times, and switch between Bedside and Cart Communication Modes. Confirm that the configuration function is working by performing this operation several times. Select Bedside Communication Mode.
7. Connect lead wires from the cardiac monitor to the Monitor Transceiver, matching colors and lead markings.

C. Patient Transceiver Set Up /Power on Test

1. Insert the fully charged battery into the Patient Transceiver.
2. Remove 5 Lead LeadWear® Disposable from package. Insert 5 Lead LeadWear® Connector into connector port, matching connector colors and connector keys.
3. Confirm that all indicators light for approximately one second and an audible BEEP is heard, this is a user interface test. Confirm that the Low Battery Charge indicator is OFF.
4. Connect electrode snaps on 5 LeadWear® Disposable to Patient Simulator.

D. Transceiver Synchronizing – Single Bedside

1. Remove blue Token from the Bedside Monitor Transceiver. Confirm "Insert Token Into Patient Transceiver" Status indicator on Monitor Transceiver glows SOLID YELLOW.
2. Insert Token into Token port on the side of Patient Transceiver. Wait for Return Token To Monitor Transceiver Status indicator on Patient Transceiver to FLASH YELLOW. Confirm that Patient Transceiver produces a single BEEP when Token is fully seated.
3. Remove Token from Patient Transceiver. Confirm that Return Token To Monitor Transceiver Status indicator goes OFF.
4. Place Token back into Token port of the Bedside Monitor Transceiver. Confirm that the Monitor Transceiver produces a single BEEP, and that the "Insert Token Into Patient Transceiver" Status indicator goes OFF. Confirm that Communication Status indicators on both Transceivers flash GREEN (over "Bedside" on the Patient Transceiver). Confirm that the ECG/Respiration signals appear on the cardiac monitor display, and that the ECG/Respiration signals agree with the ECG Patient Simulator settings.

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E. Monitor Transceiver Set Up – Cart 12 Lead

1. Insert blue Token into Token port on the top of the ECG machine Monitor Transceiver.
2. Place the third partially charged battery in the ECG machine Monitor Transceiver, confirming that the plastic film contact cover has been removed.
3. Press Power On/Off switch. Confirm that all indicators light for approximately one second and an audible BEEP is heard, this is a user interface test. Confirm that the YELLOW Low Battery Charge indicator is flashing and that an audible tone continues to beep.
4. Connect the ECG machine Monitor Transceiver to the Power Supply and plug to AC Power.
5. Insert the gree configuration Token marked ECG in the Token port on the top of the Monitor Transceiver. The Monitor Transceiver will BEEP 4 times, and change the ECG mode, which will be illuminated on the front panel. Confirm that the configuration function is working by performing this operation several times. Select ECG 12-Lead mode.
6. Insert the yellow configuration Token Marked Bedside/Cart into the Token Port on the top of the Monitor Transceiver. The Monitor Transceiver will BEEP 4 times, and switch between Bedside and Cart Communication Modes. Confirm that the configuration function is working by performing this operation several times. Select Cart Communication Mode.
7. Connect lead wires from the 12 lead ECG machine to the ECG machine Monitor Transceiver, matching colors and lead markings.
8. Remove Precordial LeadWear® Disposable from package and connect electrode snaps on Precordial LeadWear® Disposable to Patient Simulator (do not connect V1-RED lead).
9. Insert Precordial LeadWear® connector into GREEN connector port. Leave 5 Lead LeadWear® Connector in place.

F. Transceiver Synchronizing – Cart 12 Lead

1. Remove blue Token from the ECG machine Monitor Transceiver. Confirm "Insert Token Into Patient Transceiver" Status indicator on this Monitor Transceiver glows SOLID YELLOW.
2. Insert Token into Token port on the side of Patient Transceiver. Wait for Return Token To Monitor Transceiver Status indicator on Patient Transceiver to FLASH YELLOW. Confirm that Patient Transceiver produces a single BEEP when the Token is fully seated.
3. Remove Token from Patient Transceiver. Confirm that Return Token To Monitor Transceiver Status indicator goes OFF.
4. Place Token back into Token port of the ECG machine Monitor Transceiver. Confirm that the Monitor Transceiver produces a single BEEP, and that the "Insert Token Into Patient Transceiver" Status indicator goes OFF. Confirm that Communication Status indicators on all three transceivers flash GREEN (both "Bedside" and "Cart" on the Patient Transceiver). Confirm that the proper ECG

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signals appear on both ECG equipment displays, and that the ECG signals agree with the ECG Patient Simulator settings.

5. Wait for two minutes. After two minutes, the ECG machine Monitor Transceiver stops receiving signals from the Patient Transceiver. Confirm that the Communication Status indicator on the ECG machine Monitor Transceiver SOLID YELLOW, the Communication Status indicator on the cardiac Monitor Transceiver flashes GREEN, and only the "Bedside" Communication Status indicator on the Patient Transceiver flashes GREEN.

G. Transceivers – Confirm Low Battery Charge Indicators on Patient Transceiver

1. Disconnect Monitor Transceivers from both ECG monitors and turn equipment OFF.
2. Remove the batteries from all Transceivers. Disconnect the Monitor Transceivers from the Power Supply and plug to AC power.
3. Place the partially charged battery in the Patient Transceiver. Confirm that the Low Battery Charge indicator flashes YELLOW and an audible tone continues to beep. Remove the LeadWear® connector to turn Patient Transceiver OFF.
4. Place the fully charged battery in one Monitor Transceiver. Turn the Transceiver ON and confirm that all Low Battery Charge and Battery Charging indicators are OFF. Repeat with the other Monitor Transceiver.
5. Place the fully charged battery back into the Patient Transceiver.
6. Connect both Monitor Transceivers to the Power Supplies and plug to AC power. Confirm that the GREEN Battery Charge indicator is flashing. Let batteries charge for 8 hours before use.

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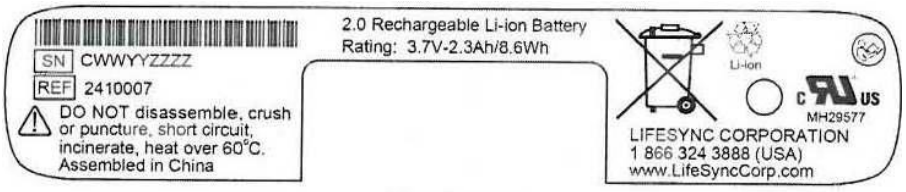
Rechargeable Battery

Battery Life

It is recommended that batteries be discarded after one year of normal use (400 discharge cycles). Recycle or dispose of discarded batteries according to national, state and local regulations.



CAUTION:
- Remove the plastic film cover from the battery contacts before using.
- Do not short the battery terminals.
- Do not try to connect a LifeSync® Rechargeable Battery with any device other than a LifeSync® Monitor Transceiver or a LifeSync® Patient Transceiver.
- Do not expose to high temperature (above 26°C / 80°F).

WARNING:
- Do not incinerate, submerge, crush, disassemble or autoclave the battery.
- Do not recharge or reuse battery that has been submerged; discard or recycle it immediately.

Battery Storage

Batteries should be removed from Patient Transceivers and stored separately when not in use for more than a few days.

NOTE: The Patient Transceiver will continue to draw a small amount of power from the battery even when LeadWear® Disposables are not connected and all indicators are off. If batteries are stored for more than a month they will need charging.

NOTE: The Monitor Transceiver will continue to draw a small amount of power from the battery even when Monitor Transceiver is turned off. If the Monitor transceiver is turned off, the AC adaptor is removed and the batteries are stored for more than a month they will need charging.

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NOTE: Storing the battery for a long period of time without use may degrade the battery capacity.

CAUTION:
- Store batteries between -10°C and 26°C/ 50°F and 80°F.
- Keep batteries in low humidity location with little temperature variation.
- Keep batteries away from direct sunlight.

Patient Cables and Cable Adapters Maintenance

Before use, check that the product is intact and clean.

WARNING: Do not use if you see signs of deterioration or damage. Make sure there are no cracks, cuts, tears, or breaks in the insulation and that the connectors are in good condition.

Use only recommended cleaning substances and disinfectants listed in the cleaning section of this Manual. Others may cause damage not covered by warranty, reduce the useful life of the product, or cause safety hazards.

CAUTION: Never immerse or soak the Patient Cables and Cable Adapters.

CAUTION: Do not sterilize Patient Cables and Cable Adapters by autoclave, radiation or steam.

Always follow and retain the instructions accompanying the cleaning and disinfecting substances you are using. Dilute according to the Manufacturer's instructions.

Keep Patient Cables and Cable Adapters free of dust and dirt; clean and disinfect the Patient Cables and Cable Adapters after each use.
Protect the Patient Cables and Cable Adapters from strong UV radiation.

NOTE: LifeSync® Patient Cables and Cable Adapters are non-sterile, reusable and latex free.

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Cleaning LifeSync® System Components

Cleaning the Transceivers, Battery and Power Supply

The LifeSync® Patient Transceiver, Monitor Transceiver, Rechargeable Battery and Power Supply may be cleaned as needed by wiping with a nearly-dry cloth, moistened with one of the following cleaning solutions: warm water and soap, Cidex®, 70% isopropyl alcohol. Thoroughly wipe off any excess cleaning solution with a dry cloth.

CAUTION:
- Do not use the following solvents for cleaning the transceivers: butyl alcohol, ethanol, Freon, bleach, acetone, hydrogen peroxide.
- Use of any of these solvents may lead to deterioration of plastic components.
- Do not sterilize by autoclave, radiation or steam any LifeSync® System Components.

CAUTION:
- Transceivers should have batteries installed whenever they are cleaned.
- Batteries may be cleaned separately but care must be taken to avoid wetting the metal battery contacts.

WARNING:
- Do not allow liquid into battery slots, battery contacts, connector ports, and Token ports or any other openings or crevices.
- Do not immerse any LifeSync® System Component in any liquid.

Cleaning and Disinfecting Patient Cables and Cable Adapters

Clean the Patient Cables and Cable Adapters by wiping with a lint free cloth, moistened with warm water and mild detergent or soap solution.

CAUTION: Never use oils or strong solvents.

Allow Patient Cables and Cable Adapters to dry completely after cleaning.

Disinfect the Patient Cables and Cable Adapters by using a chemical disinfectant such as ethanol, propanol, or glutaraldehyde.

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CAUTION: Use only recommended cleaning substances and disinfectants. Others may cause damage not covered by warranty, reduce the useful life of the product, or cause safety hazards.

Cleaning the LeadWear® Disposables

LifeSync® LeadWear® Disposables are intended for single patient use only. They may be wiped with a nearly-dry cloth, moistened with warm water. If a LeadWear® Disposable becomes badly soiled, it should be replaced.

NOTE: These recommendations are provided for guidance only. The actual cleanliness of devices depends upon techniques and actual cleaning practices employed by the user.

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Troubleshooting

In each section, start at the top of each solution set and work down.

Symptom	Cause	Solution
Patient Transceiver won't turn On	• 5 Lead LeadWear® blue connector not fully inserted or defective (curling, scratches, etc.)	• Remove, inspect for damage and replace or reinsert LeadWear® Connector correctly; replaced if damaged
	• Battery is discharged or defective	• Charge battery or replace with fully charged battery and ensure it is properly latched. • Replace defective battery
	• Battery contacts covered	• Uncover and charge battery
	• End cap damaged	• Check end cap, replace Patient Transceiver if damaged *
	• Patient Transceiver failure	• Replace Patient Transceiver *
Monitor Transceiver won't turn On	• Power supply not connected to Monitor Transceiver or AC outlet	• Connect power supply to Monitor Transceiver and AC outlet, verify green A/C indicator lit
	• Monitor Transceiver is not On	• Turn Monitor Transceiver On with power on/off switch
	• Faulty AC outlet	• Use another AC outlet
	• Battery contacts covered (if running on battery)	• Uncover and charge battery
	• Faulty power supply	• Replace power supply
	• Monitor Transceiver failure	• Replace Monitor Transceiver *
Patient Transceiver Intermittent On/Off	• 5 Lead LeadWear® blue connector not fully inserted or defective (curling, scratches, etc.)	• Remove, inspect for damage and replace or reinsert LeadWear® Connector correctly; replace if damaged
	• Battery not fully inserted	• Ensure battery is fully inserted and latched
	• Faulty battery	• Replace battery
	• End cap damaged	• Check end cap, replace Patient Transceiver if damaged *
	• Patient Transceiver failure	• Replace Patient Transceiver *

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Symptom	Cause	Solution
Monitor Transceiver Intermittent On/Off	• Power supply not properly connected to Monitor Transceiver or AC outlet	• Ensure power supply properly connected to Monitor Transceiver and AC outlet, verify green A/C indicator lit
	• Battery not fully inserted (if running on battery)	• Ensure battery is fully inserted and latched
	• Faulty battery	• Replace battery
	• Faulty power supply	• Replace power supply
	• Monitor Transceiver failure	• Replace Monitor Transceiver *
Transceivers Red Service light On	• Unit needs servicing	• Replace Patient Transceiver or Monitor Transceiver *
All LEDs On	• Unit needs servicing	• Replace Patient Transceiver or Monitor Transceiver *
No or Intermittent Communication "sync" between Transceivers	• Token not fully inserted on Monitor Transceiver	• Fully insert token on Monitor Transceiver and synchronize if needed
	• Patient Transceiver or Monitor Transceiver not turned On	• Ensure both units are turned On and synchronize if needed
	• Out of range or at edge of range	• System range exceeded – move patient back within 30 feet of Monitor Transceiver
	• Permanent communication will drop briefly (3 to 4 seconds) while initiating Cart 12 lead Monitoring	• Intermittent condition may last up to 20 seconds if temporary communication cannot be established
	• 5 Lead LeadWear® blue connector not fully inserted or defective (curling, scratches, etc.)	• Remove, inspect for damage and replace or reinsert LeadWear® Connector correctly; replaced if damaged
	• End cap damaged	• Check end cap, replace Patient Transceiver if damaged *
	• Patient Transceiver failure	• Replace Patient Transceiver *
	• Monitor Transceiver failure	• Replace Monitor Transceiver *
Patient Transceiver beeping	• Low or faulty battery	• Re-charge battery, or replace with fully charged battery
	• Battery not fully inserted	• Ensure battery is fully inserted and latched

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Symptom	Cause	Solution
Patient Transceiver beeping Continued	• Turns on and off intermittently	• Check 5 Lead LeadWear® connector for damage, replace if needed. • Check end cap, replace Patient Transceiver if damaged *
	• Patient Transceiver failure	• Replace Patient Transceiver *
Monitor Transceiver beeping	• Power supply not connected to Monitor Transceiver or AC outlet, resulting in low battery	• Connect power supply to Monitor Transceiver and AC outlet, verify green A/C indicator lit
	• Battery not fully inserted (if running on battery)	• Ensure battery is fully inserted and latched
	• Faulty battery	• Replace battery
	• Faulty power supply	• Replace power supply
	• Monitor Transceiver failure	• Replace Monitor Transceiver *
Patient Transceiver All LEDs Intermittent On/Off	• 5 Lead LeadWear® blue connector not fully inserted or defective (curling, scratches, etc.)	• Remove, inspect for damage and replace or reinsert LeadWear® Connector correctly; replaced if damaged
	• Battery not fully inserted	• Ensure battery is fully inserted and latched
	• Faulty battery	• Replace battery
	• End cap damaged	• Check end cap, replace Patient Transceiver if damaged *
	• Patient Transceiver failure	• Replace Patient Transceiver *
Monitor Transceiver All LEDs Intermittent On/Off	• Power supply not properly connected to Monitor Transceiver or AC outlet	• Ensure power supply properly connected to Monitor Transceiver and AC outlet, verify green A/C indicator lit
	• Battery not fully inserted (if running on battery)	• Ensure battery is fully inserted and latched
	• Faulty battery	• Replace battery
	• Faulty power supply	• Replace power supply
	• Monitor Transceiver failure	• Replace Monitor Transceiver *
Battery does not last 16 hours on Patient Transceiver or 8 hours on Monitor Transceiver	• Battery not fully charged at start when replaced	• Ensure battery is fully charged at installation
	• Battery at end of life, or faulty	• Replace battery

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Symptom	Cause	Solution
Monitor Transceiver not charging battery, or Monitor Transceiver battery charge indicator not lit	• Power supply not connected to Monitor Transceiver or AC outlet	• Connect power supply to Monitor Transceiver and AC outlet, verify green A/C indicator lit
	• Battery not fully inserted	• Ensure battery is fully inserted and latched
	• Battery contacts covered	• Uncover and charge battery
	• Faulty battery	• Replace battery
	• Faulty power supply	• Replace power supply
	• Faulty AC outlet	• User another AC outlet
	• Monitor Transceiver failure	• Replace Monitor Transceiver *
V Lead Off (for 5 Lead only)	• Monitor Transceiver in 12 LEAD ECG mode	• Switch to 5 LEAD ECG mode
	See No ECG or Leads Off section	
No ECG or Leads Off	• Electrode(s) faulty, not properly placed or skin not properly prepped	• Replace electrode(s) and ensure proper skin prep and placement
	• Poor LeadWear® Disposable connection to electrode(s)	• Ensure that LeadWear® Disposable is firmly attached to electrode snaps
	• LeadWear® connectors not fully inserted or defective (curling, scratches, etc.)	• Remove, inspect for damage and replace or reinsert LeadWear® Connector correctly; replaced if damaged
	• LeadWear® damaged	• Inspect for damage and replace if needed
	• End cap damaged	• Check end cap, replace Patient Transceiver if damaged *
	• Patient Transceiver battery is discharged or defective	• Charge battery or replace with fully charged battery and ensure it is properly latched. • Replace defective battery
	• Power supply not connected to Monitor Transceiver or AC outlet	• Connect power supply to Monitor Transceiver and AC outlet, verify green A/C indicator lit
	• Monitor Transceiver is Off	• Turn Monitor Transceiver On with power on/off switch
	• Incorrect 5 Lead or 12 Lead ECG mode selected	• Ensure proper 5 Lead or 12 Lead ECG mode selected
No ECG or Leads Off Continued	• Lead wire(s) damaged or poor connections to Monitor	• Check lead wire(s) are free of damage and firmly connected to

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Symptom	Cause	Solution
	Transceiver	Monitor Transceiver. Replace if damaged
	• Trunk cable damaged or disconnected from lead wires or ECG monitor	• Check trunk cable for damage or disconnection. Replace if damaged
	• Out of range or at edge of range	• System range exceeded – move patient back within 30 feet of Monitor Transceiver
	• Transceivers not synchronized	• Re-synchronize
	• ECG monitor not operating properly	• Check ECG monitor
	• Patient Transceiver failure	• Replace Patient Transceiver *
	•Monitor Transceiver failure	• Replace Monitor Transceiver *
Inverted signal on ECG equipment	• Incorrect lead wire connections to Monitor Transceiver	• Check lead wire(s) are in the correct lead and properly placed on the Monitor Transceiver
	• LeadWear® leads incorrectly placed	• Check LeadWear® leads are properly placed
Intermittent ECG, Artifact and Noise	• Electrode(s) faulty, not properly placed or skin not properly prepped	• Replace electrode(s) and ensure proper skin prep and placement
	• Poor LeadWear® Disposable connection to electrode(s)	• Ensure that LeadWear® Disposable is firmly attached to electrode snaps
	• LeadWear® connectors not fully inserted or defective (curling, scratches, etc.)	• Remove, inspect for damage and replace or reinsert LeadWear® Connector correctly; replaced if damaged
	• LeadWear® damaged	• Inspect for damage and replace If needed
	• End cap damaged	• Check end cap, replace Patient Transceiver if damaged *
	• Battery not fully inserted	• Ensure battery is fully inserted and latched
	• Patient Transceiver battery is discharged or defective	• Charge battery or replace with fully charged battery and ensure it is properly latched. • Replace defective battery
Intermittent ECG, Artifact and Noise Continued	• Power supply not connected to Monitor Transceiver or AC	• Connect power supply to Monitor Transceiver and AC

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Symptom	Cause	Solution
	outlet	outlet, verify green A/C indicator lit
	• Monitor Transceiver is Off	• Turn Monitor Transceiver On with power on/off switch
	• Incorrect 5 Lead or 12 Lead ECG mode selected	• Ensure proper 5 Lead or 12 Lead ECG mode selected
	• Lead wire(s) damaged or poor connections to Monitor Transceiver	• Check lead wire(s) are free of damage and firmly connected to Monitor Transceiver. Replace if damaged
	• Lead wire(s) too close to AC power source	• Separate lead wires from AC power source
	• Trunk cable damaged or not properly connected to lead wires or ECG monitor	• Check trunk cable for damage and proper connection. Replace if damaged
	• Out of range or at edge of range	• System range exceeded – move patient back within 30 feet of Monitor Transceiver
	• Token not fully inserted on Monitor Transceiver	• Fully insert token on Monitor Transceiver and synchronize if needed
	• Transceivers not synchronized	• Re-synchronize
	• Motion artifact	• Advise patient to be still
	• ECG monitor not operating properly	• Check ECG monitor
	• Patient Transceiver failure	• Replace Patient Transceiver *
	• Monitor Transceiver failure	• Replace Monitor Transceiver *
No, Intermittent or Noisy Respiration	• Electrode(s) faulty, not properly placed or skin not properly prepped	• Replace electrode(s) and ensure proper skin prep and placement
	• LeadWear® leads incorrectly placed	• Check LeadWear® leads are properly placed, alternative placement may interfere with respiration
	• Poor LeadWear® Disposable connection to electrode(s)	• Ensure that LeadWear® Disposable is firmly attached to electrode snaps
No, Intermittent or Noisy Respiration Continued	• LeadWear® Blue connector not fully inserted or defective	• Remove, inspect for damage and replace or reinsert

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Symptom	Cause	Solution
	(curling, scratches, etc.)	LeadWear® blue connector correctly; replaced if damaged
	• LeadWear® damaged	• Inspect for damage and replace if needed
	• End cap damaged	• Check end cap, replace Patient Transceiver if damaged *
	• Lead wire(s) damaged or poor connections to Monitor Transceiver	• Check lead wire(s) are free of damage and firmly connected to Monitor Transceiver. Replace if damaged
	• Lead wire(s) too close to AC power source	• Separate lead wires from AC power source
	• Trunk cable damaged or disconnected from lead wires or ECG monitor	• Check trunk cable for damage or disconnection. Replace if damaged
	• Respiration function not selected on ECG equipment	• Select proper respiration function settings
	• Patient Transceiver failure	• Replace Patient Transceiver *
	• Monitor Transceiver failure	• Replace Monitor Transceiver *
Patient Cables and Cable Adapters No ECG or Respiration	• Electrode(s) faulty, not properly placed or skin not properly prepped	• Replace electrode(s) and ensure proper skin prep and placement
	• LeadWear® leads incorrectly placed	• Check LeadWear® leads are properly placed, alternative placement may interfere with respiration
	• Poor LeadWear® Disposable connection to electrode(s)	• Ensure that LeadWear® Disposable is firmly attached to electrode snaps
	• LeadWear® connectors not fully inserted or defective (curling, scratches, etc.)	• Remove, inspect for damage and replace or reinsert LeadWear® Connector correctly; replaced if damaged
	• LeadWear® damaged	• Inspect for damage and replace if damaged
	• Trunk cable damaged or disconnected from Cable Adapter or ECG monitor/telemetry box	• Check trunk cable for damage or disconnection. Replace if damaged
Patient Cables and Cable	• Respiration function not selected on ECG equipment	• Select proper respiration function settings

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Symptom	Cause	Solution
Adapters No ECG or Respiration Continued	• ECG monitor or telemetry box not operating properly	• Check ECG monitor or telemetry box
	• Patient Cable or Cable Adapter Failure (housing damage, broken wire(s), socket damage, plug damage etc.)	• Replace Patient Cable and Cable Adapter *
Patient Cables and Cable Adapters Intermittent, Noisy ECG or Respiration	• Electrode(s) faulty, not properly placed or skin not properly prepped	• Replace electrode(s) and ensure proper skin prep and placement
	• LeadWear® leads incorrectly placed	• Check LeadWear® leads are properly placed, alternative placement may interfere with respiration
	• Poor LeadWear® Disposable connection to electrode(s)	• Ensure that LeadWear® Disposable is firmly attached to electrode snaps
	• LeadWear® connectors not fully inserted or defective (curling, scratches, etc.)	• Remove, inspect for damage and replace or reinsert LeadWear® Connector correctly; replaced if damaged
	• LeadWear® damaged	• Inspect for damage and replace if damaged
	• Trunk cable damaged or not properly connected to Cable Adapter or ECG monitor/telemetry box	• Check trunk cable for damage and proper connection. Replace if damaged
	• Lead wire(s) too close to AC power source	• Separate lead wires from AC power source
	• ECG monitor or telemetry box not operating properly	• Check ECG monitor or telemetry box
	• Patient Cable or Cable Adapter Failure (housing damage, broken wire(s), socket damage, plug damage etc.)	• Replace Patient Cable or Cable Adapter *

***If problem cannot be resolved contact LifeSync Corporation Customer Service toll-free at 866-ECG-3888 (866-324-3888) or email us at CustomerService@LifeSyncCorp.com**

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Technical / Specifications

Specifications

The LifeSync® System meets all applicable requirements for Cardiac Monitors, Heart Rate Meters and Alarms as well as applicable requirements for Diagnostic Electrocardiographs per ANSI/AAMI EC13:2002 and ANSI/AAMI EC11:1991 respectively.

Parameter	Specification	
	5 LEAD MODE (continuous monitoring)	**12 LEAD MODE (diagnostic ECG)**
Number of Channels, single-ended, wrt RL	4	9
Channels Active	LL, LA, RA, RL, V	LL, LA, RA, RL, V1-V6
Input Dynamic Range	± 300 mV DC; 10 mV p-p AC	
ECG Signal Slew Rate	320 mV/s maximum	
Input Impedance	>2.5 MΩ at 100 Hz	
Leadoff Sense Current	50 nA for LL, LA, RA, V1-V6 up to 500 nA for RL, V	
Frequency Response Method A per EC11:1991 Triangle Response Method D per EC13:2002	 DC-40 Hz 0.0 ± 0.25 dB 40-150 Hz 0.0 ± 1 dB 10% maximum reduction 20 ms vs 200 ms triangle wave (System test with HP Page Writer 100)	
Line Filter (60 Hz)	None	
Ch-Ch Signal noise	30 µV p-v maximum per EC13:2002	
Multi-channel Crosstalk	≤ 0.5 % maximum	
ECG Signal Gain WRT RL	1.00 ± 0.01 V/V (Measured at 10 Hz)	
Ch-Ch Gain Difference	0.1% maximum @ DC-150 Hz	
CM Rejection	<1 mV output with 20 Vrms input at 60 Hz (tested with Welch Allyn Propaq per EC13:2002)	
Leadoff: • Leadoff sensed by Patient Transceiver • Leadoff simulated by Monitor Transceiver	1. Leadoff sensing performed individually by PT on all 10 patient electrode connections; respectively leadoff electrodes in MT. 2. Leadoff of all electrodes simulated during loss of radio link. 3. Leadoff of all electrodes simulated during loss of power to either PT or MT. Note: Power to leadoff circuit in MT is backed-up by internal long-life lithium coin cell batteries.	
DC Offset – any channel	± 5 mV maximum	

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Parameter	Specification	
Pacer Pulse Detection, Transmission, and Reconstruction	Signals on RA, LA, & LL channels only are acquired at ~16,000 sps and monitored for high slew rates (>10,000 mV/s). When high slew rate is detected, a high resolution 6 ms data sample is acquired and transmitted without Captures and transmits 6 ms. Detects and transmits pacemaker pulses of amplitude 2-700 mV of duration 0.2-2.0 ms and of amplitude 3-700 mV of duration 0.1-0.2 ms.	
Pacer Pulse Function Trigger Slew Rate	Pacer Pulse functions triggers when ECG signal slew rate exceeds 10,000 mV/s	
Signal Latency due to radio	500 ms maximum	
Operating Battery	Voltage	3.6 VDC
	Capacity	2200 mA-hr
	Technology	Rechargeable Lithium-Ion
Operating Battery Life	Patient Transceiver	Monitor Transceiver
	16 hrs maximum	8 hrs maximum
Size	8 x 12.5 x 3 cm (W x H x T)	8.5 x 16 x 4 cm (W x H x T)
Weight (includes battery)	240 g	280 g
Rated Voltage/Current	3.6 VDC, 0.25 A	5.5 VDC .75 A
Operating Temperature	0 to 45 °C	
Storage Temperature	-20 to 70 °C	
Atmospheric Pressure	700-1060 mbar	
Housing Material	ABS	
Radio Protocol Class Range Operating Frequency Channels Power output level PT MT Bluetooth® Revision	Bluetooth® wireless technology Class 2 10 m 2.402-2.480 GHz 79 1MHz channels -8.3 dBm maximum (.38 mW) -2.8 dBm maximum (.72 mW) V1.1	
Water Ingress Rating	IPX1 per IEC 60529 (for both PT & MT)	
Patient Applied Parts type	Defib proof Type CF per EN60601-1	
Defibrillation Proof	Withstands 400 J per IEC 60601-2-27	
Recovery time after defibrillation exposure	5 seconds, maximum	
Safety	EN60601-1, IEC60601-2-27, UL 60601-1 CSA 22..2 No 601.1 IEC 601.2.27	
EMC	EN 60601-1-2:2001	
Respiration Specifications: Sensing Electrodes Excitation Frequency Patient Risk Current Frequency Response Input-Output Dynamic Range Base Impedance Range Respiration Output	 RA-LL (in Patient Transceiver) 32 kHz 10 µA max with AAMI ES-1 test load - 0.25-2.0 Hz (±6 dB) 8 ohm p-v maximum 0-2000 ohms Modulated digital potentiometer in series with RA electrode (in MT)	

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Parameter	Specification
Minimum Respiration DC coupled impedance before Lead Fail	>1.2 kOhms

EMC Information for the LifeSync System 2.1

♦ *Use of Power Supplies*

The LifeSync System 2.1 is compliant for EMC with the following power supplies:

Cat. #	***Description***	***Input Voltage***	***Output Voltage***	***EMC Compliance***	***Note Configuration Tested***
LS-132	*RDKN55-12M V1;JeromeLinear Power Supply*	*120 VAC @ 60 Hz*	*5.5 VDC @ 750 mA*	*Yes*	
LS-432	*WSC155MC, Jerome Industries Medical Power Supply*	*120 VAC @60 Hz*	*5.5 VDC @ 750 mA*	*Yes*	

♦ *Use of Batteries*

The LifeSync System 2.1 is compliant for EMC with the following battery pack:

Cat. #	***Description***	***Type***	***Rating***	***EMC Compliance***	***Note Configuration Tested***
LS-405	*2.1 Transceiver Battery*	*Lithium Ion*	*3.7V-2.3Ah*	*Yes*	

♦ *Stacked Equipment*

WARNING: This equipment should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, the Transceivers should be observed to verify normal operation in the configuration in which it will be used.

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Guidance and Manufacturer's Declaration –Electromagnetic Emissions		
The LifeSync System 2.1 is intended for use in the electromagnetic environment specified below. The customer or the user of the LifeSync System 2.1 should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	The LifeSync System 2.1 uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The LifeSync System 2.1 is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Complies	

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Guidance and Manufacturer's Declaration –Electromagnetic Immunity			
The LifeSync System 2.1 is intended for use in the electromagnetic environment specified below. The customer or the user of the LifeSync System 2.1 should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines Not Applicable for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV line(s) to line(s) ±2 kV line(s) to earth	±1 kV line(s) to line(s) ±2 kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % U_T (>95 % dip in U_T) for 0,5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 sec	<5 % U_T (>95 % dip in U_T) for 0,5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the LifeSync System 2.1 requires continued operation during power mains interruptions, it is recommended that the Monitor Transceiver be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A / m	Not Applicable	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE U_T is the a.c. mains voltage prior to application of the test level.			

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Guidance and Manufacturer's Declaration –Electromagnetic Immunity			
The LifeSync System 2.1 is intended for use in the electromagnetic environment specified below. The customer or the user of the LifeSync System 2.1 should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the LifeSync System 2.1, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = 1.2\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	3 V/m	$d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2,5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, [a]should be less than the compliance level in each frequency range. [b] Interference may occur in the vicinity of equipment marked with the following symbol: If operating under conditions according to the EMC-standard 60601-1-2 (Radiated Immunity 3V/m), field strengths at this level may cause erroneous measurements of respiration at various frequencies when the LifeSync® Wireless System is used together with some Monitor Systems. The criteria for success that was used for the respiration portion of the LifeSync System 2.1 for radiated immunity (3 V/m) was oriented toward patient respiration rate monitoring. The respiration rate as displayed on the patient monitor tested could not deviate more than ± 20% with a 10 second settling time for transmitter switching.
NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/wireless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the LifeSync System 2.1 is used exceeds the applicable RF compliance level above, the LifeSync System 2.1 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the LifeSync System 2.1. [b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

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Recommended Separation Distances between portable and mobile RF communications equipment and the LifeSync System 2.1

The LifeSync System 2.1 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the LifeSync System 2.1 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the LifeSync System 2.1 as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2,5 GHz $d = 2.3\sqrt{P}$
0,01	0.12	0.12	0.23
0,1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

♦ *Bluetooth Class 2 Radio for Communication*

The LifeSync System 2.1 intentionally receives RF electromagnetic energy for patient monitoring and diagnosis using Bluetooth Class 2 radios. Although no issues have been observed with coexistence with 802.11 b,g equipment, the user should be aware that the LifeSync System 2.1 operates in the same frequency band as 802.11 b,g. The RF band of reception for the LifeSync System 2 is 2.400 GHz to 2.4835 GHz. The overall band of the signal is 83.5Mhz with 79 channels of adaptive frequency hopping. Each channel has a bandwidth of 1 Mhz .

The LifeSync System 2.1 includes low power Bluetooth class 2 RF transmitters for patient monitoring and diagnosis. Although no issues have been observed with coexistence with 802.11 b,g equipment, the user should be aware that the LifeSync System 2.1 operates in the same frequency band as 802.11 b,g. The RF band of transmission is 2.400 GHz to 2.4835 GHz. The overall band of the signal is 83.5Mhz with 79 channels of adaptive frequency hopping. Each channel has a bandwidth of 1 Mhz . The maximum radiated output power is 2.5 mW or 4 dBm.

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Manufacturer's Information

The LifeSync® System is covered by one or more of the following Patents: 5,862,803; 5,957,854; 6,289,238; 6,441,747; 6,496,705; 6,577,893; 6,611,705. Additional patents are pending.

LIFESYNC CORPORATION EXPRESSLY DISCLAIMS ANY IMPLIED WARRANTY OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE.

The LifeSync® System complies with UL 60601-1, CSA C22.2 No. 601.1, EN 60601-1 and EN 60601-2-27. LifeSync® LeadWear® Disposables comply with ANSI/AAMI EC 53: 1995 and EC 53/A1: 1998.

The LifeSync® System complies with Part 15 of the FCC rules.
Operation is subject to the following two conditions:

(1) This device may not cause harmful interference, and
(2) This device must accept any interference received, including interference that may cause undesired operation.

The information contained in this document is subject to change without notice. LifeSync Corporation makes no Warranty of any kind with respect to this information.

For more information concerning the LifeSync® System, contact:

LifeSync Corporation
Fort Lauderdale, Florida USA
within the US: 954-745-3510
Toll Free: 866-ECG-3888 (866-324-3888)
www.LifeSyncCorp.com

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Reorder Information

Printed copies of this User Manual are available directly from LifeSync Corporation. Reorder # LS-216

LifeSync® System components can be reordered from LifeSync Corporation, by calling toll free 866-ECG-3888 (866-324-3888).

For convenience, LifeSync® Reorder codes and/or Model Numbers appear on all LifeSync® System components.

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